

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : HEINRICH BOLLMANN ET AL.
Serial No. : 09/456,371 **Group:** 1771
Atty. No : 12010 **Examiner:** Victor S. Chang
Filed : December 8, 1999
Title : Composite Elements Comprising (i) Thermoplastic Polyurethane
and (ii) Microcellular Polyurethane Elastomers

AMENDED BRIEF ON APPEAL

Mail Stop Appeal Brief - Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Notice of Non-Compliant Appeal Brief, mailed July 3, 2007, and subsequent to the filing of the Notice of Appeal on April 26, 2007, Applicant now submits a brief in support of the appeal in response to the Final Rejection set forth in the Office Action dated September 25, 2007 and a one-month extension of time to reply to the Notice of Non-Compliance. Only a single copy of this Appeal Brief is being submitted in accordance with 37 C.F.R. §41.37. The required fee under §41.20(b)(2) has previously been submitted.

As set forth in MPEP 1204.01 and in compliance with 37 CFR 41.20, any previously paid fees submitted with an appeal brief will be applied to the new appeal brief on the same application as long as a final Board decision has not been made on the prior appeal.

Currently, the fee associated with a filing an Appeal Brief is \$500.00. On

December 23, 2004, Applicant filed an Appeal Brief with the fee of \$500.00. On August 25, 2005 the Applicant filed a Request for Continued Examination (RCE) and voluntarily dismissed the pending appeal.

Since a final Board decision was not made on the prior appeal, Applicants believe that no fee is currently due with the filing of the subject Appeal Brief. However, should a fee in fact be due, the Commissioner is hereby authorized to charge such fees or credit any overpayments to Deposit Account 08-2789.

Real Party in Interest

The inventors assigned this application to BASF Aktiengesellschaft as evidenced by an assignment recorded at reel 010464, frame 0286.

Related Appeals and Interferences

There are no related appeals or interferences.

Status of Claims

Claims 19, 20, 22, 23, and 30 are on appeal and are attached hereto in the Appendix. Claims 1-18, 21, and 24-29 have been cancelled. Claim 23 stands finally rejected under 35 U.S.C. §112. Claims 19, 20, 22, 23, and 30 stand finally rejected under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. §103(a).

Status of Amendments

All amendments have been entered and are reflected in the claims in the Appendix.

Summary of Claimed Subject Matter

Claim 19 claims a composite damping element received in a transverse link, a longitudinal link, a triangular link, a rear-axle subframe, a stabilizer, a spring-strut support, or a shock-absorber. The composite damping element comprises i) a rigid thermoplastic polyurethane molding and ii) a flexible microcellular polyurethane elastomer layer (*see page 1, lines 5-15 and page 2, lines 13-25 of the originally filed specification*). The rigid thermoplastic polyurethane molding (i) has a thickness of from 2 to 10 mm. The flexible microcellular polyurethane elastomer layer (ii) is chemically bonded to and in direct contact with at least one surface of the rigid thermoplastic polyurethane molding such that the microcellular polyurethane elastomer layer dampens and absorbs vibrations of the transverse link, the longitudinal link, the triangular link, the rear-axle subframe, the stabilizer, the spring-strut support, or the shock-absorber while supported by the rigid thermoplastic polyurethane molding. (*see page 9, lines 4-15 of the originally filed specification and Figures 1-3*).

Grounds of Rejection to be Reviewed on Appeal

Whether claim 23 is properly rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Whether claims 19, 20, 22, 23, and 30 are not anticipated under 35 U.S.C. §102(b) by Renzo (French Patent 2559862), or in the alternative, non-obvious under 35 U.S.C. §103(a) over Renzo.

Argument

Rejection of claim 23 under 35 U.S.C. §112

The Examiner contends that nowhere in the original specification is there support for the structural element “elastomer layer is bonded to an outer surface of said molding.”

In accordance with MPEP 2163.06, “...information contained in *any one* of the specification, claims or drawings of the application as filed *may be added to any other part* of the application without introducing new matter” (emphasis added). Further, “[t]he ‘written description’ requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor’s obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed.” *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005). To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

The subject application is directed toward a composite damping element received in one of a transverse, longitudinal, or triangular link, a rear-axle subframe, a stabilizer, a spring-strut support, and a shock-absorber capable of replacing rubber-metal damping elements. More specifically, the composite damping element comprises a microcellular polyurethane elastomer layer in direct contact with a thermoplastic polyurethane (TPU)

molding, as described in the examples, see page 10, lines 14-18.

The specification as originally filed does not limit the configuration or orientation of the thermoplastic polyurethane molding and the microcellular polyurethane elastomer layer. It is only necessary to bond the elastomer layer in direct contact with the at least one surface of the molding. Thus, the specification as originally filed has implicit support for any orientation, including the elastomer layer bonded to an outer or an inner surface of the molding. Additional support can be found at the following: Page 1, lines 20-34; Page 4, lines 43-47, Page 5, lines 1-5; Page 9, lines 4-16; Page 9, lines 22-27; Page 10, lines 14-36.

Further, as described in the application as originally filed on page 1, lines 23-26, damping elements are well known to those of ordinary skill in the art as shown in Exhibit A, which includes portions of an English version of "Fahrwerktechnik: Radaufhängungen", 2nd Edition, ed. Prof. Dipl. -Ing. Jormsen Reimpell, Vogel Buchverlag Würzburg. In other words, Exhibit A identifies what is known to one of ordinary skill in the art at the time of filing the application as it relates to the claimed invention of replacements for well known damping elements.

Specifically, Applicant directs the Examiners attention to pages 13, 205, 369 and 370 which are attached in Exhibit A. Exhibit A illustrates numerous prior art damping elements having different orientations and configurations of the rigid metal and flexible rubber. Page 13 illustrates one damping element, shown as a shock-absorber bearing in Figure 1.10, having rubber supported both on an inner face of one metal and an outer face of another metal. Referring now to Figure 3.85 on page 205, a transverse link bearing is shown having two rubber parts 4 around a metal inner tube 1. The rubber 4 is vulcanized to and surrounds an outer face of the inner tube 1 and an inner face of the

ring 2. With reference to Figure 5.45 on page 369, an eye-type joint for a shock-absorber is shown having rubber surrounding an outer face of a metal tube and adhered to an inner face of a metal plate. Figure 5.46 on page 370 illustrates a pin-type joint that includes rubber on an inner face of one metal plate and an outer face of another metal plate.

The Examiner cites to page 10, lines 30-31, of the specification as originally filed, “[t]he composite elements consisting of two TPU specimens which had been adhesively-bonded by microcellular polyurethane” and merely concludes that this clearly shows elastomer bonded to an inner surface.

Applicant disagree that this example, cited by the Examiner, limits the invention. As discussed at page 10, lines 30-31, of the specification as originally filed, this example was utilized to determine the strength of the bond of the microcellular polyurethane to the TPU. In fact, this example adequately describes the configuration of one of the prior damping elements described above on page 369 having rubber contacting the inside of one metal part and contacting the outside of another metal part. Thus, the passage identified by the Examiner does not exclude the limitation of “elastomer layer is bonded to an outer surface of said molding” and in fact supports Applicants arguments that such a limitation was described in sufficient detail that one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention.

Those of ordinary skill in the art, upon reading the subject application, specifically, page 9, lines 4-9, in view of knowledge common to those skilled in the art, as evidenced by “Fahrwerktechnik: Radaufhängungen”, would find adequate support for the structural element “elastomer layer is bonded to an outer surface of said molding” of claim 23. Thus, it is appreciated that those of ordinary skill in the art recognize that

the necessary structure, or configuration, to replace any such prior art rubber-metal composites is inherent in the composite damping element of the subject invention. Accordingly, it is believed that the 35 U.S.C. §112 rejection is overcome.

Rejection of claims 19, 20, 22, 23, 30 under 35 U.S.C. §102(b)

It is well known that rejection of a claim under 35 U.S.C. §102 requires that each and every limitation be found in the cited reference. If even a single limitation of the rejected claim is not found in the cited reference a rejection under 35 U.S.C. §102 is improper and must be withdrawn. To anticipate a claim, a single source must contain all of the elements of the claim. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (C.C.P.A. 1978). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. *See Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984). Moreover, the single source must disclose all of the claimed elements “arranged as in the claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1548, 220 U.S.P.Q. 193, 198 (Fed. Cir. 1983).

Claim 19 claims a motor vehicle composite damping element comprising i) a *rigid* thermoplastic polyurethane molding having *a thickness of from 2 to 10 mm* and ii) a *flexible* microcellular polyurethane elastomer layer chemically bonded to and in direct contact with *at least one* surface of the *rigid* thermoplastic polyurethane molding. The

rigid thermoplastic polyurethane molding *supports* the flexible microcellular polyurethane elastomer layer *while dampening and absorbing vibrations* occurring within the transverse link, the longitudinal link, the triangular link, the rear-axle subframe, the stabilizer, the spring-strut support, or the shock-absorber.

With reference to the discussion above, it is well known that damping elements for a transverse link, a longitudinal link, a triangular link, a rear-axle subframe, a stabilizer, a spring-strut support, or a shock-absorber of a motor vehicle have heretofore been manufactured from rubber-metal composites. The prior art rubber-metal composite used in the shock-absorber of the motor vehicle has the metal portion supported by a shaft within the shock-absorber and the rubber portion positioned to absorb and dampen vibrations received by the shock-absorber. The *rigid* thermoplastic polyurethane molding has replaced the metal component and the *flexible* microcellular layer has replaced the rubber component. As discussed at length in the specification as originally filed, these prior art rubber-metal composites have disadvantages that include high density of the metal constituents, short service life of the rubber, and loss of adhesion between the rigid metal and the flexible rubber (*see page 1, lines 20-34 of the originally filed specification*). The subject invention overcomes these disadvantages.

Renzo, on the other hand, discloses a composite shock absorber, such as a jounce bumper, that is well known to those of ordinary skill in the art. The shock absorber includes a cellular elastic 51 surrounded by a thermoplastic polyurethane bellow 50. Referring to Figure 6 of Renzo (which was included with Applicant's response of February 23, 2006), the shock absorber is shown in a compressed state. As can be seen, the polyurethane bellow 50 is also compressed. Therefore, the polyurethane bellow 50 is

flexible to accommodate such compression.

The Examiner contends that the flexible polyurethane bellow 50 is solid and thus rigid. Besides the fact that Renzo simply does not indicate that its bellow 50 is rigid, the Examiner goes on further to disregard what is well known to those of ordinary skill in the art. The difference between a rigid thermoplastic polyurethane molding and a flexible microcellular polyurethane elastomer layer as used in the context of the subject invention are clear to one of ordinary skill in the art. The rigid thermoplastic polyurethane molding is replacing a metal component. The metal component is rigid, even though metal can be liquid if exposed to high enough temperatures. In the prior art, the metal component supports the rubber component. Rubber is well known to be flexible, especially in applications that dampen vibrations between two components. The flexible microcellular polyurethane elastomer layer replaces the rubber of the prior art damping elements.

Webster dictionary defines rigid as “very firm rather than pliant in composition or structure : lacking or devoid of flexibility : inflexible in nature” and defines flexible as “characterized by ready capability for modification or change, by plasticity, pliancy, variability, and often by consequent adaptability to new situations”.

The Examiner attempts to distort the flexible polyurethane bellow 50 of Renzo into the rigid thermoplastic polyurethane molding merely because it is solid. However, such a distortion can not be permitted. The disclosure of Renzo provides the flexible thermoplastic polyurethane bellow 50 about the flexible cellular elastic 51. As indicated above, Renzo does not disclose, teach, or suggest that the flexible thermoplastic polyurethane bellow 50 is rigid.

Moreover, Renzo does not anticipate under the requirements of §102 the claimed thickness of the rigid thermoplastic polyurethane molding between 2 and 10 mm. In fact, the Examiner does not cite to any portion of Renzo for this limitation and the Examiner has not provided any discussion whatsoever in the prior rejection for the thickness of the rigid thermoplastic polyurethane molding as claimed.

Renzo also does not disclose any composite damping element to dampen and absorb vibrations occurring within the transverse link, the longitudinal link, the triangular link, the rear-axle subframe, the stabilizer, the spring-strut support, or the shock-absorber. The Examiner cites to Renzo for the mere disclosure of a well known shock absorber, i.e., jounce bumper, which has not previously been formed of metal supporting a rubber component.

Accordingly, Renzo does not disclose a rigid thermoplastic polyurethane molding as now claimed. Therefore, the 35 U.S.C. §102 rejection is believed to be overcome.

Rejection of claims 19, 20, 22, 23, 30 under 35 U.S.C. §103(a)

Lack of Teaching, Suggestion, or Motivation

Applicant respectfully submits that the requirements to establish a *prima facie* case of obviousness have not been satisfied. Specifically, a sufficient teaching, suggestion, or motivation to make the modification as suggested by the Examiner has not been provided. The motivation to modify Renzo must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. The mere fact that Renzo can be so modified would not

have made the modification obvious unless Renzo suggested the desirability of the modification.

When applying 35 U.S.C. §103, the following tenets of patent law *must* be adhered to:

(A) The claimed invention *must be considered as a whole*;

(B) The references *must be considered as a whole* and must suggest the desirability and thus the obviousness of making the combination;

(C) The references must be viewed *without the benefit of impermissible hindsight* vision afforded by the claimed invention; and

(D) Reasonable expectation of success is the standard with which obviousness is determined. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986). The law is further set forth in the Manual for Patent Examining Procedure (MPEP) at §2142 “Legal Concept of *Prima Facie* Obviousness”.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not be based on applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also *In re Sang Su Lee*, 277 F.3d 1338 (Fed. Cir. 2002), citing *Brown & Williamson Tobacco Corp. v. Phillip Morris, Inc.*,

229 F.3d 1120, 1124-25 (Fed. Cir. 2000).

The Court of Appeals for the Federal Circuit (CAFC) recently reiterated the requirements required for making an obviousness determination in In re Kahn, 441 F.3d 977 (Fed. Cir. 2006), which is attached as Exhibit B. The CAFC stated that most inventions arise from a combination of old elements and each element may often be found in the prior art; however, mere identification in the prior art of each element is *insufficient* to defeat the patentability of the combined subject matter as a whole.

The CAFC also stated that to establish a prima facie case of obviousness based on a combination of elements disclosed in the prior art, a basis must be articulated. This requires the Examiner to explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious. The “motivation-suggestion-teaching” requirement protects against *the entry of hindsight* into the obviousness analysis, a problem which §103 was meant to confront. The same standard for combining references is equally applicable to modifying a single reference to arrive at the claimed invention.

In Alza Corp. v. Mylan Laboratories Inc., 80 USPQ2d 1001 (Fed. Cir. 2006), which is attached as Exhibit C, the CAFC further stated that the basis includes (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. The CAFC stated that legal determinations of obviousness should be based on evidence rather than on mere speculation or conjecture.

The CAFC continued “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with

some rational underpinning to support the legal conclusion of obviousness. This requirement is as much rooted in the Administrative Procedure Act [for our review of Board determinations], which ensures due process and non-arbitrary decision making, as it is in §103.”

With reference now to the alternative rejection set forth by the Examiner, it is not obvious to modify Renzo to arrive at the claimed invention. First, when viewing the claimed invention as a whole, the subject invention claims a replacement for well known metal-rubber damping elements comprising a *rigid thermoplastic polyurethane molding that supports a flexible microcellular polyurethane elastomer layer* such that the flexible microcellular layer dampens and absorbs vibrations occurring within the transverse link, the longitudinal link, the triangular link, the rear-axle subframe, the stabilizer, the spring-strut support, or the shock-absorber. When viewing Renzo as whole and without impermissible hindsight, Renzo merely discloses a shock absorber to absorb shock formed from a flexible bellow 50 that must be able to compress and distribute the shock to a cellular elastic 51.

The Examiner has not articulated a basis and has not explained the reasons one of ordinary skill in the art would have been motivated to modify Renzo to render the claimed invention obvious. The Examiner has merely identified the portions of the claimed elements in Renzo, i.e., a cellular portion and a thermoplastic portion, and relies on impermissible hindsight to argue that Renzo renders the claimed invention obvious.

The Examiner has not provided any discussion as to why it would be obvious to modify Renzo. Applicants submit that Renzo teaches away from modifying Renzo to arrive at the claimed invention because the bellow 50 must be flexible in order to absorb

shocks. If the bellow 50 were rigid, then the bellow 50 would not be compressible and would not be able to absorb shock. Therefore, Renzo teaches away from forming the bellow 50 from a rigid material.

Impermissible Use of Hindsight

The use of hindsight is not permissible when making an obviousness determination. The CAFC stated,

Determination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. There must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor. See Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc. , 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed.Cir. 1994) (“When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination.”); Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 935, 15 USPQ2d 1321, 1324 (Fed.Cir. 1990) (the prior art must suggest to one of ordinary skill in the art the desirability of the claimed composition); Interconnect Planning Corp. v. Feil , 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed.Cir. 1985). ” ATD Corp. v. Lydall, Inc., 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed. Cir. 1998). (attached as Exhibit D.)

It is respectfully submitted that the modification of Renzo employs impermissible hindsight and does not consider the claimed invention as a whole. In other words, the claimed invention is being analyzed element by element as a roadmap to find the prior art components and the Examiner is discounting the value of modifying these elements in a new way to achieve a new result.

In the subject invention, the novel and unique composite damping element provides for a replacement for prior metal-rubber damping elements. Therefore, it is respectfully submitted that the Examiner has failed to provide any suggestion or

motivation to modify Renzo to arrive at the subject invention as claimed without impermissible hindsight.

One skilled in the art confronted with the problem facing the inventor, namely to develop a replacement for metal-rubber damping elements, would not be motivated to modify the teachings Renzo without a reasonable and articulated basis, which is lacking.

Each and Every Feature Not Disclosed

Further, even if one assumes that Renzo could be modified, the modification does not disclose, either expressly or inherently, each and every limitation as claimed in the subject application and the *prima facie* case of obviousness has still not been established. As discussed above, Renzo does not disclose, teach, or suggest the claimed thickness of the rigid thermoplastic polyurethane molding ***between 2 and 10 mm***. Renzo also does not disclose any composite damping element to dampen and absorb vibrations occurring within the transverse link, the longitudinal link, the triangular link, the rear-axle subframe, the stabilizer, the spring-strut support, or the shock-absorber.

As such, even when modified, Renzo fails to disclose, teach, or suggest each and every limitation of the claimed invention. In view of the above, the 35 U.S.C. §103 rejection should be withdrawn.

CLOSING

For the reasons set forth above, the rejections of claims 19, 20, 22, 23, and 30 must be reversed.

Respectfully submitted,

HOWARD & HOWARD ATTORNEYS, P.C.

August 27, 2007

Date

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KKH/

CLAIMS APPENDIX

Claims 1-18 (Cancelled).

19. (Previously Presented) A motor vehicle composite damping element received in a transverse link, a longitudinal link, a triangular link, a rear-axle subframe, a stabilizer, a spring-strut support, or a shock-absorber of a motor vehicle, said composite damping element comprising:

i) a rigid thermoplastic polyurethane molding having a thickness of from 2 to 10 mm, and

ii) a flexible microcellular polyurethane elastomer layer chemically bonded to and in direct contact with at least one surface of said rigid thermoplastic polyurethane molding such that said microcellular polyurethane elastomer layer dampens and absorbs vibrations of the transverse link, the longitudinal link, the triangular link, the rear-axle subframe, the stabilizer, the spring-strut support, or the shock-absorber while supported by said rigid thermoplastic polyurethane molding.

20. (Previously Presented) The composite element of Claim 19 wherein said elastomer has a density of from 300 to 700 kg/m³, a tensile strength to DIN 53571 of from 3 to 8 N/mm², an elongation at break to DIN 53571 of from 350 to 550%, a tear propagation resistance to DIN 53515 of from 8 to 30 N/mm, and a rebound resilience to DIN 53512 of from 50 to 60%.

Claim 21 (Cancelled).

22. (Previously Presented) The composite element of Claim 19 wherein said elastomer layer is bonded to an inner surface of said molding.

23. (Previously Presented) The composite element of Claim 19 wherein said elastomer layer is bonded to an outer surface of said molding.

Claims 24-29 (Cancelled).

30. (Previously presented) The composite element of Claim 19 wherein said thermoplastic polyurethane molding is formed from isocyanates and isocyanate reactive components in a ratio of isocyanate groups to isocyanate reactive groups of greater than 1.06:1 such that said excess isocyanate groups are available for chemically bonding with said microcellular polyurethane elastomer layer.

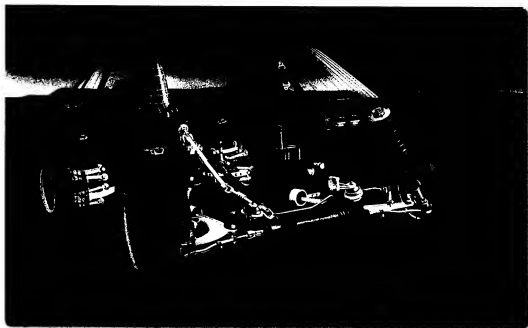
EVIDENCE APPENDIX

- Exhibit A: Portions of an English version of “Fahrwerktechnik: Radaufhängungen”, 2nd Edition, ed. Prof. Dipl. –Ing. Jornsens Reimpell, Vogel Buchverlag Wurzburg
- Exhibit B: *In re Kahn*, 441 F.3d 977 (Fed. Cir. 2006)
- Exhibit C: *Alza Corp. v. Mylan Laboratories Inc.*, 80 USPQ2d 1001 (Fed. Cir. 2006)
- Exhibit D: *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534 (Fed. Cir. 1998)

EXHIBIT A

ENGINEERING PRINCIPLES **SECOND EDITION**

The Automotive Chassis



J. REIMPELL H. STOLL J.W. BETZLER

Bast Corp.

Desk Copy

The Automotive Chassis: Engineering Principles

SECOND EDITION

Chassis and vehicle overall
Wheel suspensions and types of drive
Axle kinematics and elastokinematics
Steering - Springing - Tyres
Construction and calculations advice

Prof. Dipl.-Ing. Jörnßen Reimpell

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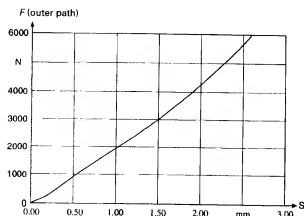
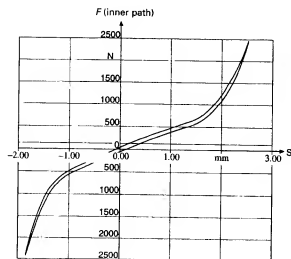
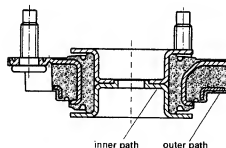
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Fig. 1.10 The dual path top mount support of the Ford Focus (1998) manufactured by ContiTech Formteile GmbH. The body spring and shock-absorber forces are introduced into the body along two paths with variable rigidity. In this way, it is possible to design the shock-absorber bearing (inner element) in the region of small amplitudes with little rigidity and thus achieve good insulation from vibration and noise as well as improve the roll behaviour of the body. With larger forces of approximately 700 N and above, progression cams, which increase the rigidity of the bearing, come into play. A continuous transition between the two levels of rigidity is important for reasons of comfort. The bearing must have a high level of rigidity in a transverse direction in order to ensure that unwanted displacements and hence changes in wheel position do not occur. The forces of the body springs are directed along the outer path, which has a considerably higher level of rigidity.



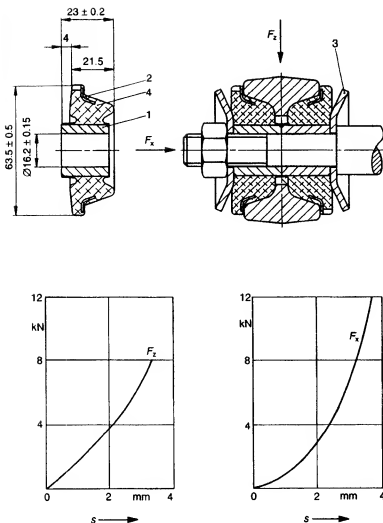
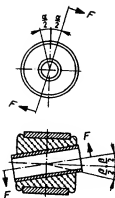


Fig. 3.85 Mounting of the anti-roll bar fitted at the front in the transverse links on the Audi 6 (built until 1996) (Fig. 1.57). The two rubber parts in the suspension control arms are vulcanized to the inner tube 1 and ring 2. Under the influence of longitudinal forces F_x , one part comes into contact at the dome-shaped washer 3 and the other part relaxes. As can be seen on the left, the rubber part 4 projects beyond the sleeve 1; when fitted this achieves the necessary pre-tensioning. Ring 2 ensures that it sits firmly in the suspension control arm, so that the mounting can transmit vertical forces F_z without complying too much. The diagrams show the longitudinally progressive characteristic curve and the almost vertical linear characteristic curve of both bearings when fitted (illustration: Lemförder Fahrwerktechnik).

Fig. 5.45 The eye-type joint has 35 mm to 36 mm outside diameter, a hole of $10^{+0.15}$ mm or $12^{+0.15}$ mm and is 32 mm wide. The maximum approved distortion angles are $\alpha/2 = \pm 15^\circ$ and the cardan (conical) angles $\beta/2 = \pm 4^\circ$.



distortion, when the vehicle is running, and premature shock absorber wear be avoided.

5.6.7.2 Eye-type joints

The requirements are best met by rubber joints. Figure 5.47 shows, on the top and bottom of the damper, the type of suspension most used: the eye-type joint, sometimes also known as a ring joint. The most common size in passenger cars is 32 mm wide, 35 mm to 36 mm diameter and has a 10 mm or 12 mm fixing hole with a $+0.15$ mm tolerance (Fig. 5.45). If compression stops are housed in the shock absorber or if spring forces are also concentrated in the mountings, 40–60 mm wide joints may be necessary (Fig. 5.29).

The joint itself consists of a rubber bush that is in high radial pre-tension between the outermost ring and the pressed-in inner tube. The rubber part has beads at both sides as a measure to stop it sliding out when the vehicle is moving. The size mostly used and shown in the illustration allows twisting angles up to $\alpha/2 = \pm 15^\circ$ and cardan (conical) deviations of up to $\beta/2 = \pm 4^\circ$. Greater twist angles would increase the bending moment in the piston rod and therefore need different configurations (Fig. 5.31 and Section 5.2 in Ref. [5]).

5.6.7.3 Pin-type joints

If the same angle movement occurs in all planes at the upper or lower suspension when the vehicle moves, the design solution is to use a pin-type joint (Figs 5.46 and 5.40). This allows deviations up to $\pm 6^\circ$ in all directions and consists of two rubber snubbers, one above and one below the fixing point; the snubbers can be separated or manufactured in one piece as a 'knob snubber'. The guide pin usually has a cold-formed 10 mm diameter and an M 10 \times 1 thread at the end. The rubber parts are pre-tensioned via a dished washer and (as shown in the figures) using a self-locking nut or two lock nuts. The distance between the lower edge of washer and the damper, which is important for the function, can be achieved using a loose spacer tube (usually of 2 mm wall thickness, i.e. 14 mm outside diameter) or by means of a rolled-in tube, as shown in Fig. 5.31.

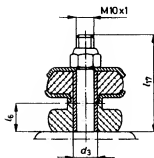


Fig. 5.46 On a pin-type joint, the preload on the rubber parts should be ensured by a spacer tube. Usually this has a wall thickness of 2 mm and 14 mm outside diameter. To avoid contact in the location hole, the upper snubber can be centred by a washer. A self-locking nut is frequently used for clamping the parts together (illustration: Sachs).

From a design perspective, it must be ensured that even at its greatest compression and twist, the side of the pin or the spacer does not come into contact with the bodywork or axle; this would lead to unpleasant noises and increased bending stress. As shown in Fig. 5.46 on the upper snubber, contact can be avoided by the use of a washer, the outer collar of which surrounds the rubber part and grips into the hole with an edge that is turned downwards. In the case of the lower snubber, the same effect is achieved by a vulcanized collar. The fixing point itself can also be designed as a 'shim'.

5.6.8 Stops and supplementary springs

Installation of any end-stops means both the damper and the suspension strut increase in length and there must be enough space in the vehicle to allow this.

5.6.8.1 Jounce stop

Figure 5.43 shows the maximum jounce force 1.45 kN at $v_{D, \max} = 0.52 \text{ m s}^{-1}$. However, piston speeds of 3 m s^{-1} can occur, which lead to higher forces. If these forces can no longer be absorbed hydraulically in the shock absorber valves, jounce stops come into action (Fig. 5.9). On passenger cars and light commercial vehicles, the most economic solution is to locate the elastic limitation of the jounce travel or the 'hydraulic stop' in the damper (see also Sections 5.3 and 8.3.1 in Ref. [5]).

The other advantage is that the slight springing effect of the top and bottom damper mountings can be additionally used to damp the jouncing wheel, and so a relatively flat, more easily manufactured bumper 5 made of rubber, polyurethane or Viton, polyamide or a similar plastic is completely adequate (Figs 5.47 and 5.26). All that is needed to fit this is a groove turned into the piston rod in which the collar on the stop disc 4 is rolled or a lock washer inserted.

In the twin-tube system, when the piston rod is extended, the snubber 5 comes into contact with the piston rod guide 6 which is smooth at the bottom (Fig. 5.47), or into contact with a disc 8 protecting the set of gaskets on monotube dampers (Fig. 5.32). Figure 5.48 shows the shapes and the progressive springing curve of the 4–12 mm high snubbers.

EXHIBIT B

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > In re Kahn, 78 USPQ2d 1329 (Fed. Cir. 2006)

In re Kahn, 78 USPQ2d 1329 (Fed. Cir. 2006)

78 USPQ2d 1329

In re Kahn

U.S. Court of Appeals

Federal Circuit

No. 04-1616

Decided March 22, 2006

441 F3d 977

Headnotes

PATENTS

[1] Practice and procedure in Patent and Trademark Office —Board of Patent Appeals and Interferences — In general (►110.1101)

Patentability/Validity — Obviousness — Combining references (►115.0905)

Patentability/Validity — Obviousness — Evidence of (►115.0906)

Problem to be examined in considering motivation to combine prior art references is not specific problem solved by invention at issue, but general problem that confronted inventor before invention was made; thus, "motivation-suggestion-teaching" test asks not merely what references disclose, but whether person of ordinary skill in art, possessed with understandings and knowledge reflected in prior art and motivated by general problem facing inventor, would have been led to make claimed combination, and from this it may be determined whether overall disclosures, teachings, and suggestions of prior art, and level of skill in art, support legal conclusion of obviousness.

[2] Patentability/Validity — Obviousness — Combining references (►115.0905)

Substantial evidence supports conclusion that person of ordinary skill in art would have been motivated to combine teachings of prior art patent, which claims acoustical imaging system for use by visually impaired individuals, with teachings of two primary references to achieve invention of application claiming "reading machine" for use by blind persons, since prior patent teaches that its invention relates to augmentation of vision of those who have lost vision or have had their visual faculties diminished, that it is useful in teaching such persons "to apprehend the position of a virtual sound source as representing a point in space," and that it may be used as "rudimentary reading device," and since skilled artisan, who knows of "learning machine" that is capable of reading word aloud by selecting word on screen at which user is looking and seeks to provide visually-impaired user better control over word localization, would have reason to solve that problem by adding two-dimensional sound, in view of prior patent's express teaching that two-dimensional sound can be used to "substitute" for lost sense of sight, to locate point in space, and to create "rudimentary reading device" for visually impaired persons.

[3] Patentability/Validity — Obviousness — Person of ordinary skill in art (►115.0902)

Patentability/Validity — Obviousness — Combining references (►115.0905)

Board of Patent Appeals and Interferences did not overstate knowledge of person of ordinary skill in art, or employ improper hindsight, in making prima facie case of obviousness, since motivation to combine

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prior art

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references to achieve invention claimed in application was articulated and placed on record.

[4] Patentability/Validity — Obviousness — Combining references (►115.0905)

Applicant's contention that person of ordinary skill in art would not have been motivated to combine prior art references to achieve invention claimed in application is without merit, since, even if applying secondary reference to primary reference resulted in device that would be less effective for primary reference's intended purpose, teaching of that reference is not limited to specific invention disclosed therein, since applicant may have envisioned something different from skilled artisan in considering secondary reference, but artisan need not be motivated to combine secondary reference for same reason contemplated by applicant, and since secondary reference does not teach away from combination with primary reference, as there is nothing in secondary reference that would discourage person of skill in art from using device taught in primary reference in claimed combination, or that would lead skilled artisan in direction divergent from path taken by applicant.

[5] Patentability/Validity — Obviousness — Long felt need (►115.0909)

Appellate court will not take judicial notice of long-felt need for device claimed in patent application, which is intended to help blind persons read, since finding either way on question of long-felt but unresolved need can reasonably be questioned, and long-felt need thus is not type of undisputed fact susceptible of judicial notice, and since precedent requires that applicant submit actual evidence of long-felt need, as opposed to argument, in that mere passage of time without claimed invention is not evidence of nonobviousness.

Case History and Disposition

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application of Leonard R. Kahn for patent on "reading machine" for use by blind persons. Applicant appeals from decision upholding rejection of claims in application for obviousness under 35 U.S.C. § 103. Affirmed.

Attorneys

Leonard R. Kahn, New York, N.Y., pro se.

John M. Whealan, solicitor; Linda Moncys Isacson and Raymond T. Chen, associate solicitors, and Mary L. Kelly, U.S. Patent and Trademark Office, Arlington, Va., for Director, U.S. Patent and Trademark Office.

Judge

Before Michel, chief judge, and Linn and Prost, circuit judges.

Opinion Text

Opinion By:

Linn, J.

Leonard R. Kahn ("Kahn") appeals from the final decision of the Board of Patent Appeals and

Interferences ("Board") concluding that claims 1–20 in patent application number 08/773,282 ("the '282 application") are unpatentable as obvious under 35 U.S.C. § 103.¹ Because the factual findings underlying the Board's conclusion are supported by substantial evidence, and because the Board did not commit legal error in concluding that the claims would have been obvious, we affirm.

¹ The Board also affirmed its own rejection of claims 21 and 22 as being non-enabled under 35 U.S.C. § 112, ¶ 1; however, in his opening brief on appeal Kahn withdrew those claims, leaving only claims 1–20 before us.

BACKGROUND

I. A. The Invention

The '282 application, filed on December 24, 1996 as a continuation-in-part of a series of continuing applications dating back to 1989, involves a "reading machine" that may be used by the blind. Prior to the application, machines that employed memory and display components by which material could be "read" using hand-held optical pens and speech synthesizers were known in the art. While a user can control these devices by hand to repeat words and to read at various speeds, such control is cumbersome, which makes it difficult for a blind user to study complex publications. Kahn addressed this problem and claims invention in a device that is operated by eye control and sound localization such that it can read out loud the word "looked at" by the user.

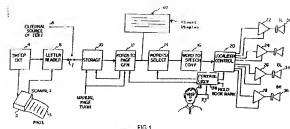
Kahn treats claims 1–20 as a group with claim 1 being representative:

1. A reading machine suitable for use by totally blind individuals for reading the complete text, or a selected portion thereof, of a document stored in storage means, at the option of the user, comprising:

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- (a) means of storing at least a portion of the text of the document to be read,
- (b) means for retrieving a selected portion of said stored text made available for immediate "reading,"
- (c) means for producing an acoustical display of the selected portion of said stored text, in a page-like format,
- (d) means for determining the location on the acoustical display towards which the user is "looking," and
- (e) means for generating speech sounds verbalizing the word that is formatted to appear on the acoustical display at the location the user is "looking" towards.

A preferred embodiment of the '282 patent is illustrated below in Figure 1.



In operation.

[The information being "read" ... is fed through intermediate storage means to speech synthesizer means for converting the written information to electrical waves representing speech sounds. These electric waves are fed to ... a four speaker array wherein the speakers are located in a fashion so that the artificial sound image can be placed at various points on the artificial screen or page allowing the user to hear the words at the desired locations. These locations would be selected by the user looking at a specific location on the artificial screen or page.

The user would then move his or her eyes to "look" where the next word would be expected to appear, i.e., directly to the right of the spoken word. This would then cause the next word to be "spoken" and the sound image would appear slightly to the right. This motion is achieved by energizing the four speaker array with different levels of audio power....

When the user completes the "reading" of the last word on the page, ... the reader would have the option of rereading a section on the page or causing the page to be "turned." If the user wishes to reread ..., he can direct his attention to the material to be reread by "looking" at the portion of the page where he remembers hearing the material.

On the other hand, if he wishes to continue reading the material he can turn the page by looking along the bottom line past the right hand edge of the "page". The first word on the new page would be heard when the reader directed his or her attention to the upper left hand corner of the page where the first word on the new page would be expected.

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²⁸² application at 11-13.

According to the specification, the device can employ a conventional scanner to input data; a conventional character recognition device to translate and send data to a storage device; and a page generator to take data from the storage device and format it for a visual display and for a word selector, the latter of which can send the data to a conventional speech synthesizer. After an optical sensor detects where a user is "looking" and a word is "selected" for vocalization, the synthesizer feeds an audio signal to a localizer control. Loud speakers are arranged at the corners of the "page" to allow the user to confirm localization of sound. The specification further indicates that

[t]here are a number of devices available for sensing where an individual is looking. For example, Garwin et. al. 4,595,990 ..., Anderson et. al. 4,579,533 ... and Stanton 4,322,744 More specifically, Anderson's [sic] patent discusses feed-back which may be visual, auditory or tactile to verify decisions by eye control equipment.

However, such inventions are not suitable for totally blind individuals who are not verifying where they

are looking but are using their eyes to direct which part of the artificial page should be read to produce a sound image. This makes essential a two dimensional stereo sound stage which the blind person solely depends upon.

'282 application at 16.

B. The Prior Art

The Board's rejection was based on Garwin et al., U.S. Patent No. 4,595,990 (issued June 17, 1986) ("Garwin"), in view of Anderson et al., U.S. Patent No. 4,406,626 (issued Sept. 27, 1983) ("Anderson '626"), Anderson et al., U.S. Patent No. 4,579,533 (issued April 1, 1986) ("Anderson '533"), and Stanton, U.S. Patent No. 4,322,744 (issued March 30, 1982) ("Stanton"). The Board alternatively used Anderson '626 or '533 as primary references.

Garwin discloses an eye-controlled interactive information processor that senses the portion of a visual display at which the user is looking. The processor is connected to the display, which, in turn, can be partitioned so that different information is displayed in discrete areas. By gazing in different directions, the user informs the processor of the displayed item that is selected. Garwin, col. 2, ll. 60-68. The preferred embodiment employs a reflected light eye-tracking device to determine where the user is looking. *Id.*, col. 3, l. 66-col. 4, l. 62. The eye-interactive control generally uses a technique where the user is presented with a number of targets having some meaning, such as "words or phrases" displayed on screen. *Id.*, col. 9, ll. 62-67. "Visual, auditory or tactile" feedback is then given to the user to indicate that a selection has been received. *Id.*, col. 2, ll. 10-11; col. 11, ll. 59-64. The user then can verify or cancel the selection. *Id.*, col. 10, ll. 1-6. Garwin states that "it will be apparent to one skilled in the art that ... the benefits of the invention will be achieved by many types of apparatus." *Id.*, col. 2, ll. 50-53. It can be used for "request[ing] display of a page of text from a ... table of contents," *id.*, col. 3, ll. 42-44, or "[other] presentation of textual material," *id.*, col. 10, ll. 31-33.

Anderson '626 discloses an interactive "electronic teaching aid" which enables a user viewing text on a display to designate any words or portion of text for immediate audible vocalization. Anderson '626, col. 1, l. 8; col. 2, ll. 11-17. The components include: a selector switch, which when in the "text" position, causes data to be transmitted to a monitor and displayed in legible form, *id.*, col. 3, ll. 27-31; an advance button, which when depressed allows the user to select and retrieve the next page of text from memory, *id.*, col. 3, ll. 31-41; a memory, which can store each word of the text coded for speech, *id.*, col. 3, l. 66-col. 4, l. 6; and a word designator light pen, which the user can place on a word to hear the word vocalized through the speaker, *id.*, col. 3, ll. 54-68; col. 10, ll. 51-58. Anderson '533 discloses an improved microprocessor-based version of Anderson '626. Anderson '533, col. 1, ll. 19-24, 41-56.

Stanton discloses an acoustical imaging system for use by visually impaired individuals that uses horizontal and vertical directional sound to represent visual aspects of an environment. Stanton states that a user can locate "the position of a virtual sound source as representing a point in space" such that different signals may represent different directions. Stanton, col. 1, ll. 58-61. The preferred embodiment features four loud speakers or transducers mounted at the corners of a vertical display panel. *Id.*, col. 2, ll. 54-55. When the user moves the cursor, the sound emanating

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from the speakers is phase shifted to produce a virtual sound seeming to come from a particular location related to the position of the cursor. *Id.*, col. 1, l. 66-col. 2, l. 2; col. 2, ll. 55-63. In another embodiment, a quadruphonic headset is used in place of the transducers to achieve the effect of producing a virtual sound identifying a position. *Id.*, col. 4, ll. 26-35. Stanton states that the device may be used as a "rudimentary reading device." *Id.*, col. 1, ll. 62.

C. The Board Decisions

Kahn filed the '282 application with 22 claims as a continuation-in-part of application number 07/645,102

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("the '102 application"), which was filed in 1991. The '102 application was a continuation-in-part of a series of abandoned continuing applications dating back to application number 07/338,597, which was filed in 1989. While claims 21 and 22 of the '282 application are not at issue in this appeal, the Board addressed those claims on several occasions, which led to the creation of a substantial Board history. As a result, the final decision with respect to the obviousness rejection of claims 1–20 spans three decisions, which include *Ex Parte Kahn*, No. 2004-1091 (B.P.A.I. June 30, 2004) ("2004 decision"); *Ex Parte Kahn*, No. 2000-1130 (B.P.A.I. Feb. 24, 2003) ("2003 decision"); and *Ex Parte Kahn*, No. 94-2233 (B.P.A.I. Sept. 21, 1995) ("1995 decision").

In its 1995 decision, after reversing the examiner's anticipation rejection, the Board *sua sponte* rejected the relevant claims under § 103. The Board found that Garwin taught "the concepts of determining where on a display screen a user is 'looking' ... and giving either visual or *auditory* feedback to the user" and that "[w]hile nothing specific is said as to acoustically reproducing a word displayed at that location, common sense ... indicate[s] that such an auditory feedback response is appropriate in view of such *auditory* feedback confirmation clearly suggested by Anderson '533 or '626." 1995 decision, slip op. at 5 (emphasis in original). The Board found that "to whatever extent Garwin is not concerned with text *per se*, [the Anderson] references are" and "teach the advantages of text display with audio reproduction," concluding that

the artisan would have found it to have been obvious to have modified Garwin for display of text passages and selection of works therefrom with vocalization thereof as feedback confirmation, all as taught by Anderson '626 or '533 ... [or] to have modified either of these Anderson references to use the eye control of Garwin so that the user's hands would have been free for other tasks.

Id., slip op. at 5-6. The Board found that Stanton "teaches the benefit of acoustic imaging in reading systems" and that "[i]t would have, thus, been further obvious to the artisan to add advantageous acoustic imaging to either of the above-noted modified devices of Garwin or the Anderson patents which would have word positions acoustically and visually indicated." *Id.*, slip op. at 6.

In its 2003 decision, the Board expressly incorporated the findings and rationale from both its 1995 decision and the Examiner's Answer filed on April 24, 2000. 2003 decision, slip op. at 3-4. In the Answer, the Examiner had explained that Garwin teaches "a buffer memory which stores at least a portion of the information derived from sensing means and means for subsequently retrieving the sensed information," "means for displaying stored written text," and "means for determining which word of the displayed text the user is looking towards"; that Anderson '626 teaches "means for generating speech sounds verbalizing the looked at word"; and that Stanton teaches "means for verbalizing each word the user's eyes are directed towards in two dimensional stereo." Examiner's Answer at 5-6. Rejecting Kahn's argument that hindsight drove the combination of references, the Board reiterated that the rationale of the 1995 decision was correct and explained that motivation "clearly is based upon a prospective look at the state of the art." 2003 decision, slip op. at 8-11.

The Board addressed several other arguments. First, the Board rejected the argument that the invention's intended use supports patentability, noting that "the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus [from] a prior art apparatus satisfying the claimed structural limitations." *Id.* at 5-6. Second, the Board rejected the argument that because "the purposes of the [prior art] references ... are different from the [invention's] purpose," the invention is non-obvious, explaining that "[t]he law ... does not require that references be combined for reasons contemplated

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by an inventor" and that "prior art need not suggest the same problem set forth by appellant." *Id.* at 6-7. Third, the Board rejected the arguments that features of a secondary reference be capable of incorporation into the structure of a primary reference and that the invention be suggested completely by one reference. *Id.* at 7. Finally, the Board rejected a "long-felt need" argument, explaining that Khan had not presented any objective evidence of a long-standing problem or long-standing need in the art. *Id.* at

11-12.

In its 2004 decision, the Board entered a final rejection of claims 1–20 based on its 2003 decision. Kahn timely appealed to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

II. DISCUSSION

A. The Parties' Arguments

Khan advances two main arguments. First, Khan asserts that the Board's finding of motivation to combine was unsupported by substantial evidence. Citing *In re Lee*, 277 F.3d 1338 [61 USPQ2d 1430] (Fed. Cir. 2002), and *In re Rouffet*, 149 F.3d 1350 [47 USPQ2d 1453] (Fed. Cir. 1998), Khan argues that the Board overstated the knowledge of the skilled artisan and employed improper hindsight. Specifically, Khan asserts that a skilled artisan would not have sought to augment Garwin with sound because the resulting device would be more expensive and less reliable for the purpose intended by Garwin. He contends that just because Stanton teaches use of sound to confirm a visual perception of a shape like a letter—which provides a “rudimentary” reading capability—does not mean that the reference teaches how to enable a blind user to “read” and “reread” entire words and phrases quickly. Khan further contends that Stanton teaches away from a system that employs iris eye direction sensing because Stanton requires the user to hold his head steady, because eyes are not involved in its localization procedure, and because the combined device would be expensive and inoperable. Second, Khan argues that the court should take “judicial notice” that his reading machine addresses a “long-felt, but unresolved need,” and that this consideration is sufficient to rebut a *prima facie* case of obviousness.

The Patent and Trademark Office (“PTO”) counters that *Lee* and *Rouffet* are distinguishable because here the Board identified motivations to combine the references based on specific statements in the references and on the nature of the problem to be solved. As to long-felt need, the PTO argues that Kahn proffered no actual evidence, and that Kahn's argument alone is insufficient to rebut a *prima facie* case.

B. Standard of Review

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art. 35 U.S.C. § 103(a) (2000); *Graham v. John Deere Co.*, 383 U.S. 1, 13-14 [148 USPQ 459] (1966). The ultimate determination of whether an invention would have been obvious is a legal conclusion based on underlying findings of fact. *In re Dembiczak*, 175 F.3d 994, 998 [50 USPQ2d 1614] (Fed. Cir. 1999). We review the Board's ultimate determination of obviousness *de novo*. *Id.* However, we review the Board's underlying factual findings, including a finding of a motivation to combine, for substantial evidence. *In re Gartside*, 203 F.3d 1305, 1316 [53 USPQ2d 1769] (Fed. Cir. 2000).

Substantial evidence is something less than the weight of the evidence but more than a mere scintilla of evidence. *Id.* at 1312 (citing *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229-30 (1938)). It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. *Consol. Edison*, 305 U.S. at 229-30. In reviewing the record, we must take into account evidence that both justifies and detracts from the factual determinations. *Gartside*, 203 F.3d at 1312 (citing *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 487-88 (1951)). We note that the possibility of drawing two inconsistent conclusions from the evidence does not prevent the Board's findings from being supported by substantial evidence. *Id.* Indeed, if a reasonable mind might accept the evidence as adequate to support the factual conclusions drawn by the Board, then we must uphold the Board's determination. *Id.*

C. Analysis

In assessing whether subject matter would have been non-obvious under § 103, the Board follows the guidance of the Supreme

Court in *Graham v. John Deere Co.* The Board determines “the scope and content of the prior art,” ascertains “the differences between the prior art and the claims at issue,” and resolves “the level of ordinary skill in the pertinent art.” *Dann v. Johnston*, 425 U.S. 219, 226 [189 USPQ 257] (1976) (quoting *Graham*, 383 U.S. at 17). Against this background, the Board determines whether the subject matter would have been obvious to a person of ordinary skill in the art at the time of the asserted invention. *Graham*, 383 U.S. at 17. In making this determination, the Board can assess evidence related to secondary indicia of non-obviousness like “commercial success, long felt but unresolved needs, failure of others, etc.” *Id.*, 383 at 17-18; *accord Rouffett*, 149 F.3d at 1355. We have explained that

[t]o reject claims in an application under section 103, an examiner must show an un rebutted *prima facie* case of obviousness On appeal to the Board, an applicant can overcome a rejection by showing insufficient evidence of *prima facie* obviousness or by rebutting the *prima facie* case with evidence of secondary indicia of nonobviousness.

Rouffett, 149 F.3d at 1355.

Most inventions arise from a combination of old elements and each element may often be found in the prior art. *Id.* at 1357. However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole. *Id.* at 1355, 1357. Rather, to establish a *prima facie* case of obviousness based on a combination of elements disclosed in the prior art, the Board must articulate the basis on which it concludes that it would have been obvious to make the claimed invention. *Id.* In practice, this requires that the Board “explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.” *Id.* at 1357-59. This entails consideration of both the “scope and content of the prior art” and “level of ordinary skill in the pertinent art” aspects of the *Graham* test.

When the Board does not explain the motivation, or the suggestion or teaching, that would have led the skilled artisan at the time of the invention to the claimed combination as a whole, we infer that the Board used hindsight to conclude that the invention was obvious. *Id.* at 1358. The “motivation-suggestion-teaching” requirement protects against the entry of hindsight into the obviousness analysis, a problem which § 103 was meant to confront. See 35 U.S.C. § 103 (stating that obviousness must be assessed “at the time the invention was made”); *Dembiczak*, 175 F.3d at 998 (“[I]t is this phrase that guards against entry into the tempting but forbidden zone of hindsight.” (internal quotations omitted)); Giles S. Rich, *Laying the Ghost of the Invention Requirement*, 1 APLA Q.J. 26-45 (1972), reprinted in 14 Fed. Cir. B.J. 163, 170 (2004) (“To protect the inventor from hindsight reasoning, the time is specified to be the time when the invention was made.”) (emphasis in original). The Supreme Court recognized the hindsight problem in *Graham* and proposed that “legal inferences” resulting from “secondary considerations” might help to overcome it. 383 U.S. at 36 (“[S]econdary considerations may also serve to guard against slipping into use of hindsight, and to resist the temptation to read into the prior art the teachings of the invention on issue.” (internal quotations omitted)). By requiring the Board to explain the motivation, suggestion, or teaching as part of its *prima facie* case, the law guards against hindsight in all cases—whether or not the applicant offers evidence on secondary considerations—which advances Congress’s goal of creating a more practical, uniform, and definite test for patentability. See *Dann*, 424 U.S. at 225-26 (“[I]t was only in 1952 that Congress, in the interest of ‘uniformity and definiteness,’ articulated the requirement in a statute.” (quoting S. Rep. No. 1979, at 6 (1952); H.R. Rep. No. 1923, at 7 (1952))); *Graham*, 383 U.S. at 17 (“The § 103[test], when followed realistically, will permit a more practical test of patentability.”).

Although our predecessor court was the first to articulate the motivation-suggestion-teaching test, a related test—the “analogous art” test—has long been part of the primary *Graham* analysis articulated by the Supreme Court. See *Dann*, 425 U.S. at 227-29; *Graham*, 383 U.S. at 35.² The analogous-art test

requires that the Board show that a reference is either in the field of the applicant’s endeavor or is

reasonably pertinent to the problem with which the inventor was concerned in order to rely on that reference as a basis for rejection. *In re Oetiker*, 977 F.2d 1443, 1447 [24 USPQ2d 1443] (Fed. Cir. 1992). References are selected as being reasonably pertinent to the problem based on the judgment of a person having ordinary skill in the art. *Id.* ("[I]t is necessary to consider 'the reality of the circumstances,'—in other words, common sense—in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor." (quoting *In re Wood*, 599 F.2d 1032, 1036[202 USPQ 171](C.C.P.A. 1979))). We have explained that this test begins the inquiry into whether a skilled artisan would have been motivated to combine references by defining the prior art relevant for the obviousness determination, and that it is meant to defend against hindsight. *See id.*; *In re Clay*, 966 F.2d 656, 659-60 [23 USPQ2d 1058] (Fed. Cir. 1992).³

² In *Graham*, Cook Chemical challenged the court's reliance on a reference that it believed was not in a "pertinent prior art," arguing that while the invention involved a container having a "pump sprayer," the reference related to containers having "pouring spouts." 383 U.S. at 35. In reaching the conclusion that the claimed subject matter was obvious, the Court rejected Cook's argument, explaining that the problem to be solved was a mechanical closure problem and that a closure device in such a closely related art was a pertinent reference. *Id.* Similarly, in *Dann*, the invention involved the use of automatic data processing equipment to analyze transactions within a single bank account. 425 U.S. at 227-28. The Dirk reference that the Court relied upon in making its obviousness case involved a similar system used in a non-banking context. *Id.* at 228. Citing *Graham*, the Court explained that a person of ordinary skill in the art would be aware of this reference and the Court could rely upon it in making its obviousness case because "[w]hile the Dirk's invention is not designed specifically for application to the banking industry many of its characteristics and capabilities are similar to those of respondent's system." *Id.* at 229.

³ In *In re Clay*, we reasoned that [i]f a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it. 966 F.2d at 659-60. In *In re Oetiker*, we held that "the combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness." 977 F.2d at 1447.

The motivation-suggestion-teaching test picks up where the analogous art test leaves off and informs the *Graham* analysis. To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references, the Board must provide some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct. The requirement of such an explanation is consistent with governing obviousness law, *see* § 103(a); *Graham*, 383 U.S. at 35; *Dann*, 425 U.S. at 227-29, and helps ensure predictable patentability determinations.

A suggestion, teaching, or motivation to combine the relevant prior art teachings does not have to be found explicitly in the prior art, as

the teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references.... The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.

In re Kotzab, 217 F.3d 1365, 1370 [55 USPQ2d 1313] (Fed. Cir. 2000) (internal citations omitted). However, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *See Lee*, 277 F.3d at 1343-46; *Rouffett*, 149 F.3d at 1355-59. This

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requirement is as much rooted in the Administrative Procedure Act, which ensures due process and non-arbitrary decisionmaking, as it is in § 103. See *id.* at 1344-45.

[1] In considering motivation in the obviousness analysis, the problem examined is not the specific problem solved by the invention but the general problem that confronted the inventor before the invention was made. See, e.g., *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323 [76 USPQ2d 1662] (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1372 [56 USPQ2d 1065] (Fed. Cir.

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2000) ("Although the suggestion to combine references may flow from the nature of the problem, [d]efining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness." (internal citation omitted) (quoting *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 [45 USPQ2d 1977] (Fed. Cir. 1998))); *In re Beattie*, 974 F.2d 1309, 1312 [24 USPQ2d 1040] (Fed. Cir. 1992) ("[T]he law does not require that the references be combined for the reasons contemplated by the inventor."); *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1337 [75 USPQ2d 1051] (Fed. Cir. 2005) (characterizing the relevant inquiry as "[w]ould an artisan of ordinary skill in the art at the time of the invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, [] have selected the various elements from the prior art and combined them in the manner claimed"); see also *Graham*, 383 U.S. at 35 (characterizing the problem as involving mechanical closures rather than in terms more specific to the patent in the context of determining the pertinent prior art). Therefore, the "motivation-suggestion-teaching" test asks not merely what the references disclose, but whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims. See *Cross Med. Prods.*, 424 F.3d at 1321-24. From this it may be determined whether the overall disclosures, teachings, and suggestions of the prior art, and the level of skill in the art—i.e., the understandings and knowledge of persons having ordinary skill in the art at the time of the invention—support the legal conclusion of obviousness. See *Princeton Biochemicals*, 411 F.3d at 1338 (pointing to evidence supplying detailed analysis of the prior art and the reasons one of ordinary skill would have possessed the knowledge and motivation to combine).

In this case, Khan does not dispute that each element of his claimed invention can be found in either Garwin, Anderson '533 and '626, or Stanton, or that each reference lies in the pertinent art. Nor does Khan take issue with the Board's finding that a person having ordinary skill in the art would have been motivated to modify Anderson '533 or '626 in view of Garwin, or vice versa. See *Garwin*, col. 2, ll. 50-53, col. 10, ll. 31-35 (stating that "it will be apparent to one skilled in the art that ... the benefits of the invention will be achieved by many types of apparatus" which may be "virtually [any device] susceptible of control by a computer, including ... [those geared] to presentation of textual material").

Rather, Khan's challenge to the sufficiency of the evidence supporting the Board's *prima facie* case is directed at the motivation to apply the teachings of Stanton to achieve the claimed invention. In the 1995 decision, the Board found that Stanton "teaches the benefit of acoustic imaging in reading systems." The Board carefully examined the Anderson/Garwin combination and recognized that a skilled artisan confronted with the problem faced by Kahn would have been led by the teaching of Stanton "to add advantageous acoustic imaging" to the Anderson/Garwin combination so that it would have "word positions acoustically and visually indicated."

[2] Stanton teaches that "[its] invention relates to augmentation of vision of those who have lost vision or have had their visual faculties diminished," col. 1, ll. 6-8, that it is "useful in teaching a deprivee to apprehend the position of a virtual sound source as representing a point in space," *id.*, ll. 58-59, and that it may be used as a "rudimentary reading device," *id.*, ll. 61-62. A skilled artisan, who knows of a "learning machine" that is capable of reading a word aloud by selecting the word on the screen at which the user is looking and seeks to provide a visually-impaired user better control over word localization,⁴ would have

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reason to solve that problem by adding two-dimensional sound in view of Stanton's express teaching that two-dimensional sound can be used to "substitute" for the lost sense of sight, to locate a point in space, and to create a "rudimentary reading device" for the visually impaired. *See Cross Med. Prods.*, 424 F.3d at 1323 (holding that "[o]ne of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings"). Because

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the Board need only establish motivation to combine by a preponderance of the evidence to make its *prima facie* case, *see In re Glaug*, 283 F.3d 1335, 1338 [62 USPQ2d 1151] (Fed. Cir. 2002), we conclude that substantial evidence supports the finding of a motivation to combine the teachings of Stanton to the Anderson/Garwin combination. Although a reasonable person might reach the opposite conclusion, there is far more than a "mere scintilla" of evidence present from which a reasonable mind could find a motivation to combine.

⁴ Kahn does not argue that one of ordinary skill in the art at the time of the invention would be unaware of the nature of this problem, and there is nothing in the record to suggest this to be the case, unlike the facts in the decision of our predecessor court in *In re Spinnoble*, 405 F.2d 578 [160 USPQ 237] (C.C.P.A. 1969).

[3] We reject Khan's argument that the Board overstated the knowledge of the person having ordinary skill in the art or employed improper hindsight in making its *prima facie* case. In both *Lee* and *Roufflet*, the Board recognized that the knowledge of the skilled artisan could provide the motivation to combine but concluded that no such knowledge was articulated and placed on the record. *Lee*, 277 F.3d at 1343-45; *Roufflet*, 149 F.3d at 1357-59. In this case, motivation to combine was articulated and placed on the record. As to the Anderson/Garwin combination, the Board identified the desire to free up the hands of the Anderson user as the problem confronted and found that Garwin itself evidenced the broad applicability of its optical controls to the claimed invention. As to the addition of Stanton, the Board identified express teachings in Stanton of "the benefit of acoustic imaging in reading systems" and properly related those teachings to the Anderson/Garwin combination.

[4] We find Khan's remaining arguments unpersuasive. First, even if applying Stanton to Garwin resulted in a device that would be less effective for the purpose intended by Garwin, the teaching of the Garwin reference is not limited to the specific invention disclosed. *See In re Heck*, 699 F.2d 1331, 1333 [216 USPQ 1038] (Fed. Cir. 1983) (explaining that "[t]he use of patents as references is not limited to what the patentees describe as their own inventions" (internal quotations omitted)). As noted above, Garwin states that his invention is intended to be applied to "virtually[any device] susceptible of control by a computer, including ... [those geared] to presentation of textual material," Garwin, col. 2, ll. 50-53; col. 10, ll. 31-35. Second, although Khan may have envisioned something different than the skilled artisan when he looked at Stanton because Stanton teaches only a *rudimentary* reading device, the skilled artisan need not be motivated to combine Stanton for the same reason contemplated by Khan. *See In re Beattie*, 974 F.2d 1309, 1312 [24 USPQ2d 1040] (Fed. Cir. 1992) ("As long as some motivation or suggestion to combine the references is provided by the prior art taken as a whole, the law does not require that the references be combined for the reasons contemplated by the inventor." (citing *In re Kronig*, 539 F.2d 1300, 1304 [190 USPQ 425] (C.C.P.A. 1976))). Third, Khan's argument that Stanton itself teaches away from the combination with Garwin lacks support in the reference. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 [31 USPQ2d 1130] (Fed. Cir. 1994). Nothing in Stanton can be said to discourage a person having ordinary skill in the art from using the visual-input control taught in Garwin in the claimed combination or to lead the skilled artisan in a direction divergent from the path taken by Kahn.

[5] Finally, we note that Kahn had an opportunity to rebut the Board's *prima facie* case by offering evidence of objective indicia of non-obviousness. Khan put on no evidence, but invites this court to take "judicial notice" of the long-felt but unresolved need for a device that will help the blind read. We must decline Khan's invitation for the following reasons. First, "long-felt but unresolved need" is not the kind of undisputed fact to which courts are accustomed to taking "judicial notice" because a finding either way can "reasonably be questioned." *See* Fed. R. Evid. 201(b) ("A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned."); *In re Fielder*, 471 F.2d 640, 642-43 [176 USPQ 300] (C.C.P.A. 1973) (declining to take judicial notice of prior art references that appellant submitted as objective evidence of non-obviousness because appellant did not offer references to the Board and they were not part of the record). Second, our

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precedent requires that the applicant submit actual evidence of long-felt need, as opposed to argument. This is because "[a]bsent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness." *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 [73 USPQ2d 1225] (Fed. Cir. 2004); *accord In re Wright*, 569 F.2d 1124, 1127 [193 USPQ 332] (C.C.P.A. 1977).

III. CONCLUSION

Because the factual findings underlying the Board's analysis, including the findings on motivation to combine, are supported by substantial evidence, we conclude that the Board did not err in rejecting claims 1–20 as *prima facie* obvious. Because Khan did not rebut the Board's *prima facie* case, the Board's decision is

AFFIRMED.

- End of Case -

EXHIBIT C

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > Alza Corp. v. Mylan Laboratories Inc., 80 USPQ2d 1001 (Fed. Cir. 2006)

Alza Corp. v. Mylan Laboratories Inc., 80 USPQ2d 1001 (Fed. Cir. 2006)

80 USPQ2d 1001
Alza Corp. v. Mylan Laboratories Inc.
U.S. Court of Appeals
Federal Circuit
No. 06-1019
Decided September 6, 2006

Headnotes

PATENTS

[1] Patentability/Validity — Obviousness — Person of ordinary skill in art (►115.0902)

Patentability/Validity — Obviousness — Combining references (►115.0905)

Under non-rigid "motivation-suggestion-teaching" test, suggestion to combine prior art references can be found in knowledge generally available to person of ordinary skill in art, as well as in references themselves, and expert testimony therefore is pertinent to evaluation of prima facie case of obviousness if such testimony is relevant to determining knowledge that person of ordinary skill in art would have possessed at given time; in present case, infringement defendants have established, by clear and convincing evidence, that invention of patent for extended-release oxybutynin formulation was rendered obvious by combination of prior art references, since record shows that teachings of references would have conveyed to person of ordinary skill, once motivated to use oxybutynin, reasonable expectation of success in manufacturing controlled release oxybutynin formulation, since testimony of defendant's expert supports finding that, based on oxybutynin's lipophilicity, person of skill in art would have had reasonable expectation that oxybutynin would be colonically absorbed and therefore would have been motivated to produce claimed extended release formulation, and since references cited by plaintiff are entirely consistent with that finding.

[2] Infringement — Literal infringement (►120.05)

Plaintiff failed to establish that accused extended-release oxybutynin formulation infringed patent in suit, since patent specifically requires that time-course of in vivo oxybutynin release for claimed formulation fall within certain boundaries, since plaintiff presented evidence of blood plasma concentration-versus-time profiles for both accused formulation and embodiment of formulation claimed in patent, but, even if it is assumed that drug is rapidly taken up into bloodstream upon dissolution, there is no expert testimony or other evidence to show that plasma concentration-versus-time data establishes in vivo release rates for either accused formulation or patented embodiment, and since plaintiff's evidence of in vitro dissolution rates is irrelevant absent evidence demonstrating that in vitro system is good model of actual in vivo behavior; conclusion of noninfringement does not require specific finding that two bodies of evidence presented by plaintiff are inadequate when considered both individually and in

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combination, since instant case does not present situation in which two pieces of otherwise severely inadequate evidence create great probative value synergistically.

Particular Patents

Particular patents — Chemical — Oxybutynin formulations

6,124,355, Guittard, Jao, Marks, Kidney, and Gumucio, oxybutynin therapy, judgment of invalidity and noninfringement affirmed.

Case History and Disposition

Appeal from the U.S. District Court for the Northern District of West Virginia, Keeley, C.J.

Action by Alza Corp. against Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. for patent infringement. Plaintiff appeals from judgment of invalidity and noninfringement following bench trial. Affirmed.

Attorneys

Gregory L. Diskant, Jeffrey I.D. Lewis, and Richard J. McCormick, of Patterson, Belknap, Webb & Tyler, New York, N.Y., for plaintiff-appellant.

John B. Wyss, James H. Wallace Jr., Kevin P. Anderson, and Robert J. Scheffel, of Wiley, Rein & Fielding, Washington, D.C., for defendants-appellees.

Judge

Before Gajarsa, circuit judge, Clevenger, senior circuit judge, and Prost, circuit judge.

Opinion Text

Opinion By:

Gajarsa, J.

Alza Corp. ("Alza") appeals from the district court's judgment, after a bench trial, of noninfringement and invalidity of claims 1-3, 11, 13 and 14 of U.S. Patent No. 6,124,355¹ ("the '355 patent") in favor of Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively, "Mylan"). *Alza Corp. v. Mylan Labs., Inc.*, 388 F.Supp.2d 717 (N.D.W. Va. 2005) ("*Alza II*"). The infringement arose from Mylan's filing of two Abbreviated New Drug Applications ("ANDAs") for a generic version of the once-a-day extended release formulation of the anti-incontinence drug oxybutynin, *id.* at 720, which Alza has been marketing as Ditropan XL®. *Id.* at 738. This court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(1). For the reasons stated below, we affirm the district court's judgment of noninfringement and invalidity.

¹ The '355 patent issued to Guittard et al. and was assigned to Alza.

I. BACKGROUND

This litigation arose from Mylan's and Impax's filings of ANDAs for once-daily, controlled-release oxybutynin formulations. Oxybutynin is a drug used to treat urinary incontinence. Once-a-day dosing provides the usual benefits of convenience, steady-dosing, and in addition, possibly reduced absorption of a metabolite that leads to side-effects. Claim 2 of the '355 patent is representative.

2. A sustained-release oxybutynin formulation for oral administration to a patient in need of treatment

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for urge incontinence comprising a therapeutic dose of an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt that *delivers* from 0 to 1 mg in 0 to 4 hours, from 1 mg to 2.5 mg in 0 to 8 hours, from 2.75 to 4.25 mg in 0 to 14 hours, and 3.75 mg to 5 mg in 0 to 24 hours for treating urge incontinence in the patient.

col. 17, ll. 31-38 (emphasis added).

The district court construed the '355 patent claims in its *Markman* Order, reported at *Alza Corp. v. Mylan Labs., Inc.*, 349 F.Supp.2d 1002 (N.D.W. Va. 2004) ("*Alza I*"). The court construed the word "deliver" to refer to the rate of *in vivo* release in the gastrointestinal ("GI") tract. *See id.* at 1019.

Alza did not present direct evidence that Mylan's ANDA formulation released drug in the GI tract at the rates claimed by the '355 patent. However, it did offer two other types of evidence: 1) the rate at which the generic product released oxybutynin in an *in vitro* dissolution apparatus, and 2) the rate at which the ANDA product resulted in the accumulation of oxybutynin in the bloodstream.

The district court found that Alza had failed to meet its burden of proof on infringement. The district court also found the asserted claims of the '355 patent to be invalid as both anticipated and obvious in light of the prior art. For the reasons stated below, we affirm the invalidity holding on obviousness grounds, and consequently, we do not need to reach Alza's arguments regarding anticipation. We also affirm the holding of noninfringement.

II. DISCUSSION

A. Standard of review

Infringement is a question of fact that, after a bench trial, we review for clear error. *See*,

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e.g., Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC, 350 F.3d 1327, 1338 [69 USPQ2d 1001] (Fed. Cir. 2003). Under the clear error standard, a reversal is permitted only when this court is left with a definite and firm conviction that the district court was in error. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1164 [77 USPQ2d 1865] (Fed. Cir. 2006).

As for obviousness, a claimed invention is unpatentable if the differences between it and the prior art are "such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (2000); *In re Kahn*, 441 F.3d 977, 985 [78 USPQ2d 1329] (Fed. Cir. 2006) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 13-14, [148 USPQ 459] (1966)). Obviousness is a question of law, reviewed *de novo*, based upon underlying factual questions which are reviewed for clear error following a bench trial. *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 [69 USPQ2d 1686] (Fed. Cir. 2004). These "underlying factual inquiries includ[e]: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness." *In re Dembiczyk*, 175 F.3d 994, 998 [50 USPQ2d 1614] (Fed. Cir. 1999). Similarly, "[t]he presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact," *In re Gartside*, 203 F.3d 1305, 1316 [53 USPQ2d 1679] (Fed. Cir. 2000); *accord Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1348 [53 USPQ2d 1580] (Fed. Cir. 2000), as is the presence or absence of a "reasonable expectation of success" from making such a combination, *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 [77 USPQ2d 1865] (Fed. Cir. 2006). Because "a patent retains its statutory presumption of validity, *see* 35 U.S.C. § 282, ... the movant retains the burden to show the invalidity of the claims by clear and convincing evidence as to underlying facts." *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1349 [60 USPQ2d 1001] Fed. Cir. 2001)(internal quotations omitted).

In *Graham*, the Court held that the obviousness analysis begins with several basic factual inquiries: "[1] the scope and content of the prior art are to be determined; [2] differences between the prior art

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and the claims at issue are to be ascertained; and [(3)] the level of ordinary skill in the pertinent art resolved." 383 U.S. at 17. After ascertaining these facts, the Court held that the obviousness *vel non* of the invention is then determined "against th[e] background" of the *Graham* factors. *Id.* at 17-18 (emphasis added). Clearly, the Court recognized the importance of guarding against hindsight, as is evident in its discussion of the role of secondary considerations as "serv[ing] to guard against slipping into use of hindsight and to resist the temptation to read into the prior art the teachings of the invention in issue." *Id.* at 36.

The Court of Appeals for the Federal Circuit's and its predecessor's "motivation to combine" requirement likewise prevents statutorily proscribed hindsight reasoning when determining the obviousness of an invention. *Kahn*, 441 F.3d at 986 ("[T]he 'motivation-suggesting-teaching' requirement protects against the entry of hindsight into the obviousness analysis."); *In re Fridolph*, 30 CCPA 939, 942 (1943) ("[I]n considering more than one reference, the question always is: does such art suggest doing the thing the [inventor] did."). According to the "motivation-suggesting-teaching" test, a court must ask "whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims." *Kahn*, 441 F.3d at 988 (citing *Cross Med. Prods., Inc., v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1321-24 [76 USPQ2d 1662] (Fed. Cir. 2005)).

This requirement has been developed consistent with the Supreme Court's obviousness jurisprudence as expressed in *Graham* and the text of the obviousness statute that directs us to conduct the obviousness inquiry "at the time the invention was made" 35 U.S.C. § 103. As we explained in *Kahn*,

The motivation-suggestion-teaching test picks up where the analogous art test leaves off and informs the *Graham* analysis. To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references, the Board must provide some rationale, articulation, or reasoned basis to

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explain why the conclusion of obviousness is correct. The requirement of such an explanation is consistent with governing obviousness law ...

441 F.3d at 987. We further explained that the "motivation to combine" requirement "[e]ntails consideration of both the 'scope and content of the prior art' and 'level of ordinary skill in the pertinent art' aspects of the *Graham* test." *Id.* at 986.

At its core, our anti-hindsight jurisprudence is a test that rests on the unremarkable premise that legal determinations of obviousness, as with such determinations generally, should be based on evidence rather than on mere speculation or conjecture. Our court's analysis in *Kahn* bears repeating:

A suggestion, teaching, or motivation to combine the relevant prior art teachings *does not have to be found explicitly in the prior art*, as "the teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references.... The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." However, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be *some* articulated reasoning with *some* rational underpinning to support the legal conclusion of obviousness. This requirement is as much rooted in the Administrative Procedure Act [for our review of Board determinations], which ensures due process and non-arbitrary decisionmaking, as it is in § 103.

441 F.3d at 987-88 (quoting *In re Kotzab*, 217 F.3d 1365, 1370 [55 USPQ2d 1313] (Fed. Cir. 2000)) (citations omitted) (emphases added)). There is flexibility in our obviousness jurisprudence because a motivation may be found *implicitly* in the prior art. We do not have a rigid test that requires an actual teaching to combine before concluding that one of ordinary skill in the art would know to combine

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references. This approach, moreover, does not exist merely in theory but in practice, as well. Our recent decisions in *Kahn* and in *Cross Medical Products* amply illustrate the current state of this court's views. See *Kahn*, 441 F.3d at 988 (affirming the PTO's obviousness finding, explaining that a motivation to combine may be found in implicit factors, such as the "knowledge of one of ordinary skill in the art, and [what] the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art"); *Cross Med. Prods.*, 424 F.3d at 1322 (reversing a district court ruling of nonobviousness and explaining that "the motivation to combine need not be found in prior art references, but equally can be found in the knowledge generally available to one of ordinary skill in the art" such as knowledge of a problem to be solved).

In conclusion, our approach has permitted us to continue to address an issue of law not readily amenable to bright-line rules, as we recall and are guided by the wisdom of the Supreme Court in striving for a "practical test of patentability." *Graham*, 383 U.S. at 17.

B. Description of the technology

The patent at issue is directed generally to an extended release form of oxybutynin. Because the subject matter of the patent falls roughly under the rubric of pharmacology, we give a brief orientation to the field, based upon the record. In general, when a drug is swallowed, it is (1) dissolved in the gastrointestinal ("GI") tract; (2) absorbed from the GI tract into the bloodstream; (3) distributed from the blood into body tissues; and (4) metabolized and eliminated from the bloodstream. The GI tract includes the stomach, small intestine and the colon, and orally administered drugs pass through these portions of the GI tract in turn. Drugs may be administered in different dosage forms,² which may include not only the drug itself but also ingredients intended to modulate the rate of release of the drug from the dosage form.

² Here we are discussing oral dosage forms, specifically.

Dosage forms may be described as immediate-release, e.g., such as where the drug is quickly released in the stomach, or as sustained/extended-release, where the drug is slowly released as the formulation traverses the GI tract. The rate of absorption of a drug from the GI tract into the bloodstream may change as it passes through the GI tract. The rate of absorption for a dissolved drug in a given portion of the GI tract also varies from drug to drug.

After roughly 8-12 hours a typical dosage form will reach the colon. If, hypothetically, a

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particular drug is simply not absorbed from the colon into the bloodstream, then it may make little sense to develop an extended-release dosage form that is capable of "withholding" the release of some fraction of that drug until it reaches the colon. In other words, under these hypothetical conditions, there may be little motivation to design an oral dosage form capable of releasing drug more *slowly* than over an approximately 8-12 hour time course, because such drug would be released in the colon, where it is (hypothetically) not absorbed.

The '355 patent claims an extended release oxybutynin formulation. Alza argues that one of ordinary skill in the art would not have believed that oxybutynin could be absorbed in the colon. Absent such absorption, Alza contends that one of ordinary skill in the art lacked the motivation to make the claimed extended release formulation, and that the district court therefore erred in holding that the asserted claims are invalid as obvious over the prior art. For the reasons set forth below, Alza's arguments fail.

C. Invalidity

The district court based its invalidity holding both on anticipation and obviousness grounds. Because we affirm its holding based on obviousness, we do not need to address the parties' anticipation arguments.

In finding the asserted claims of the '355 patent to be obvious, the district court considered, *inter alia*, the following prior art: U.S. Patent Nos. 5,399,359 ("the Baichwal patent"); 5,082,688 ("the Wong patent"); and 5,330,766 ("the Morella patent").

The Morella patent discloses a "sustained-release pharmaceutical composition including an active ingredient of high solubility in water" According to the specification, highly soluble drugs had posed special challenges for the development of sustained release forms, which the inventors had set out to solve. "Sustained-release" is defined as release of the active ingredient at a rate that maintains therapeutic, nontoxic blood levels "over an extended period of time e.g. 10 to 24 hours or greater." Highly water soluble drugs were considered to be those having an aqueous solubility of at least roughly 1 part in 30. The commercially available hydrochloride salt of oxybutynin is freely soluble at neutral pH. The patent uses morphine as an example of an active ingredient that can be used in its compositions. Figure 5 demonstrates that one such composition is capable of dispensing morphine at what appears to be an approximately steady rate over the course of 24 hours. Claim 2 of the patent claims "genitourinary smooth muscle relaxants" as one of several types of active ingredients to use in the dosage form identified in claim 1. The specification also identifies oxybutynin as a highly water soluble genitourinary smooth muscle relaxant. Morella also teaches that "the dissolution rate of the soluble drug at various pH's can be modified at will."

The Baichwal patent teaches a 24 hour extended release oxybutynin formulation. These formulations use an enteric-coated polymer matrix similar to Mylan's accused product. It also teaches methods of modifying the dosage forms to slow the release rates. During prosecution of the '355 patent, the inventor overcame an anticipation rejection by arguing that his invention had a release rate slower than those of the dissolution data presented in Baichwal.³ The examiner agreed and withdrew his rejection.

³ Tables 15 and 18 of Baichwal, for example, disclose *in vitro* dissolution rates in which roughly half of the drug is dissolved by four hours.

The Wong patent teaches a bilayer osmotic pump dosage form ("the OROS system") used in the preferred embodiment of the '355 patent. Wong teaches that this system can be used to deliver any drug over a 24 hour period, and Figure 11 of the patent discloses release rates falling within the claimed release rates of the '355 patent. The Wong patent does not specifically teach using oxybutynin with the claimed release technology, but it does teach using several categories of drugs of which oxybutynin is a member, such as anti-cholinergics, analgesics, muscle relaxants and urinary tract drugs.

In analyzing the obviousness issue, the district court first identified the level of ordinary skill in the art, finding the person of ordinary skill to have either an advanced degree in pharmacy, biology, chemistry or chemical engineering and at least two years of experience with controlled-release technology; or a bachelor's degree in one (or more) of those fields plus five years of experience with such technology. Second, the court examined whether there was a motivation "in the prior art or elsewhere that would have led one of the ordinary

skill in the art to combine references," *Alza II*, 388 F.Supp.2d at 737 (citing *Ruiz*, 234 F.3d at 664 (internal quotations omitted)), and with a "reasonable expectation of success," *id.* (citing *In re O'Farrell*, 853 F.2d 894, 904 [7 USPQ2d 1673] (Fed. Cir. 1988)). Third, the district court examined secondary considerations of nonobviousness. After making these factual determinations, it concluded that Mylan had established a strong *prima facie* case of obviousness, which Alza had failed to rebut through secondary considerations.

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The court concluded that Mylan had demonstrated Alza's patent to be invalid for obviousness by clear and convincing evidence.⁴ We agree.

⁴ Having reviewed Alza's sundry contentions that the district court made findings inconsistent with the appropriate burdens of proof for infringement and invalidity, we find them to be without merit.

[1] While we have carefully considered all of the parties' arguments, we discuss principally the dispute over satisfaction of one predicate to a finding of obviousness: that a person of ordinary skill in the art would have had a "motivation to combine" the prior art to achieve the claimed invention and that she would have had a "reasonable expectation of success" in doing so. As an initial matter, we agree with the district court that "on a purely mechanical level, a person of ordinary skill in the art would have a reasonable expectation of success of manufacturing a 24 hour controlled-release oxybutynin formulation ... *once motivated to use oxybutynin.*" *Id.* at 739. For example, Wong teaches a rate adjustable extended release dosing technology and release rates falling within the claimed parameters. Baichwal and Wong likewise teach ways of achieving slow rates of release, with Baichwal actually teaching extended-release oxybutynin, although arguably not as slowly as is claimed in the '355 patent.⁵

⁵ The patent examiner initially rejected the '355 patent as anticipated by Baichwal, but subsequently allowed its issuance.

Indeed, Alza's principal argument is that no one of ordinary skill in the art would have been motivated to adapt the Morella, Baichwal and Wong technology to oxybutynin *in the first place*, because a person of ordinary skill in the art would have had no reason to expect that such an extended release oxybutynin formulation would have therapeutic value. The issues, as explained above, reduce essentially to whether one of ordinary skill in the art in 1995 would have had a reasonable expectation that oxybutynin would be colonically absorbed and therefore would have been motivated to produce the claimed extended release formulation.

The district court concluded that "the weight of the evidence clearly and convincingly establishes that a person of ordinary skill in the art in 1995 would reasonably expect oxybutynin to absorb in the colon ... [and] have a reasonable expectation of success of producing a 24 hour oxybutynin formulation meeting the claims of the '355 patent."⁶ *Alza II*, 388 F.Supp.2d at 740. Alza argues, however, that the district court erred because "[t]here was no prior art evidence supporting this finding." According to Alza, "[t]here was no contemporaneous documentation supporting the view that any one factor—lipophilicity or anything else—existed to identify successful candidates for once-a-day delivery." It also argues that two prior art references "decisively undercut" the opinion of Mylan's expert, Dr. Amidon, which the district court cited in support of its conclusion. See *Alza II*, 388 F.Supp.2d at 739-740.

⁶ The '355 patent issued on September 26, 2000 and claimed priority as far back as 1995. See '355 patent, col. 1, ll. 5-12. The district court treated 1995 as the relevant date for the obviousness inquiry, see *Alza II*, 388 F.Supp.2d at 740, as do both parties in their obviousness arguments before this court. See, e.g., *Alza Reply Br.* at 13 (stating that "[t]he dispositive obviousness issue was whether colonic absorption of oxybutynin was reasonably expected in 1995") (emphasis added); *Mylan Br.* at 6 & n.2 (referring to evidence establishing "the clear expectation of one skilled in the art in 1995" and noting in a footnote that 1995 is "[t]he earliest possible date to which Alza asserts priority.") (emphasis added).

As an initial matter, it is essential to recognize that, as we have explained above, under our non-rigid "motivation-suggesting-teaching" test, a suggestion to combine need not be found in the prior art. See *Cross Med. Prods.*, 424 F.3d at 1322 ("[T]he motivation to combine need not be found in prior art references, but equally can be found in the knowledge generally available to one of ordinary skill in the art ..."). Accordingly, where the testimony of an expert witness is relevant to determining the knowledge that a person of ordinary skill in the art would have possessed at a given time, this is one kind of evidence that is pertinent to our evaluation of a *prima facie* case of obviousness. We now

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turn to consider whether the relevant evidence, including the expert testimony and the prior art, when viewed as a whole supports the findings of the district court. We conclude that the findings of the district court were not clearly erroneous.

Mylan's expert, Dr. Amidon, testified that based on its lipophilicity, he would "expect oxybutynin to be a highly permeable" compound that is "rapidly absorbed" along the length of the GI tract, including the colon. Later, when challenged about the predictive value of lipophilicity, Dr. Amidon explained, "I would say there were some unknowns, but again lipophilic drugs would be well absorbed. That would be—that was the general understanding at the time."

Although Alza argues that two prior art references "decisively undercut Dr. Amidon's hindsight opinion," these references are in fact not inconsistent with the general principle that the extent of a drug's colonic absorption correlates with its lipophilicity. Indeed, the first reference, a 1990 publication in the *Journal of Pharmaceutical Sciences*, states that "[i]n general, the more lipophilic drugs were transported rapidly." P. Artursson, *Epithelial Transport of Drugs in Cell Culture. I: A Model for Studying the Passive Diffusion of Drugs over Intestinal Absorptive (Caco-2) Cells*, 79 J. Pharm. Sci. 476, 481 (1990). Alza, however, cites this reference narrowly for its observation that a highly lipophilic analog of a particular drug did not follow the general rule that lipophilic drugs were transported more quickly. *Id.* Granted, the authors admit that "[t]he reason for this [deviation] is currently unknown," and they postulate that it may be related to a physicochemical factor other than lipophilicity, namely steric hindrance.⁷ *Id.* But the mere fact that the colonic absorption rate of a drug may be predicted most precisely by using "many factors," rather than "lipophilicity" alone, does not negate the general predictive utility of lipophilicity in estimating the extent of colonic absorption.

⁷ Dr. Chancellor, Alza's expert, likewise characterized colonic absorption as having been understood as being dependent on several physicochemical and physiological variables, of which lipophilicity was one.

The second prior art reference cited by Alza, *Absorption of Polar Drugs Following Caecal Instillation in Healthy Volunteers*, is similarly unavailing to it. Riley, et al., 6 *Aliment. Pharmacol. Ther.* 701, 705 (1992). Again, this reference teaches that while the correlation is not perfect, lipophilicity tended to suggest colonic absorption, stating that "[t]he relationship between the physical characteristics of a drug and its colonic absorption is not yet clear but studies in the rat suggest that *lipophilic drugs are well absorbed along the length of the gastrointestinal tract*, whereas hydrophobic polar drugs are absorbed much less from the colon than from the small intestine." *Id.* (emphasis added).

Far from teaching away or detracting from the weight of Dr. Amidon's testimony, these prior art references, taken as a whole, are entirely consistent with the finding that in 1995 a person of ordinary skill in the art would have expected a general, albeit imperfect, correlation between a drug's lipophilicity and its colonic absorptivity. Accordingly, we cannot perceive clear error in the district court's factual findings that while colonic absorption was not *guaranteed*, the evidence, viewed as a whole, is clear and convincing

that a person of ordinary skill in the art would nonetheless have perceived a reasonable likelihood of success and that she would have been motivated to combine prior art references to make the claimed invention.

Likewise, we find no error in the district court's consideration of secondary indicia of obviousness. We therefore affirm its legal conclusion of obviousness, finding the district court to have correctly held that Mylan met its burden of overcoming the presumption of validity that attaches to an issued patent.

D. Infringement

The '355 patent specifically describes the rate of oxybutynin release from its "extended release" formulations, requiring that the time-course of *in vivo* oxybutynin release falls within certain boundaries. That is, at certain times, the cumulative amount of dissolved (released) drug must fall within certain ranges. To prove infringement, Alza bore the burden of proving, *inter alia*, that Mylan's accused generic formulation exhibited an *in vivo* release profile falling within the claimed ranges at the relevant times.

At trial, Alza presented no direct evidence of how quickly the accused product dissolved *in vivo*. Alza II, at 722. However, it did offer two kinds of indirect evidence as measures of the rate of *in vivo* release. *Id.* First, it presented

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evidence of the blood plasma concentration versus time profiles for both the accused ANDA formulation and Ditropan, an embodiment of the '355 patent. Second, it presented evidence of the rate of release not in the GI tract but in pieces of laboratory apparatus under certain experimental conditions, so-called *in vitro* dissolution. The critical deficiency in the evidence presented by Alza was not that it was "indirect" rather than "direct," but rather that it failed to credibly link these pieces of evidence with the relevant pharmacokinetic parameter—the rate of *in vivo* dissolution in the GI tract.

Thus, the district court explained that Alza had failed to demonstrate how evidence of the rate of dissolution of drug in the GI tract could be extracted from plots of plasma concentration versus time. The district court accepted Alza's simplifying assumption about oxybutynin rapidly being absorbed following dissolution such that the rates of *in vivo* dissolution parallel the rate of drug uptake into the blood. However, it found that only one expert, Dr. Amidon, had "endorsed Alza's subjective comparison of blood plasma levels with *in vivo* release rates." As for that one expert, moreover, he "rejected the very conclusion that Alza attributed to him."

[2] Alza criticizes the district court for "fail[ing] to come to grips with the significance of the testimony" that Dr. Amidon "recanted ... immediately after he made it." Specifically, Alza urges that notwithstanding the expert's recantation, we should nonetheless draw our independent conclusions from the "point of his testimony" that release rates in blood and the appearance in the GI tract are essentially the same. We have considered Alza's arguments and find them to lack legal and factual coherency. Even if we were to presume to be experts and to apply the simplifying assumption that the drug is rapidly taken up into the bloodstream upon dissolution, it is not clear to us how to abstract from each plasma concentration versus time curve the rate of uptake into the bloodstream. This would require factoring out of the curve the effects, *inter alia*, of the elimination of drug from the bloodstream over the relevant 24 hour period. But this is not our province. Such evidence, if it exists, must have been presented at trial, or in its stead other evidence sufficient to persuade the trial court.

From what can be discerned, Dr. Amidon's immediately recanted statement appears to have been based on his comparison of the relative areas under the curves of plasma concentration versus time plots of both the accused ANDA formulation and Ditropan XL. Indeed, Alza reproduces in its appellate brief Dr. Amidon's testimony that the accused product has only 92 to 93 percent of the area under the curve of Ditropan XL. This appears to have resulted in the drawing of a line (referred to by the parties as "line A") on a plot of *in vitro* dissolution of both Ditropan XL and the accused ANDA formulation, wherein the rate of *in vitro* dissolution of Mylan's ANDA formulation has been adjusted according to that percentage. The

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basis for, and significance of, line A is simply not apparent from the record, and Alza fails to provide us with any persuasive line of argument as to how we should imbue line A with any relevant meaning. In short, we agree with Mylan that the plasma concentration versus time data fail to establish *in vivo* release rates for either Ditropan XL or the accused ANDA product.

The district court similarly found unpersuasive Alza's evidence that Ditropan XL and the accused ANDA product sometimes exhibited *in vitro* dissolution rates falling within the claims. The court cited testimony by Dr. Amidon explaining that these *in vitro* procedures are "not designed to reflect the *in vivo* dissolution process." This accords with the common sense notion that one cannot simply proclaim without proof that he has constructed an apparatus capable of mimicking pertinent environmental variables of the GI tract (along the length of the tract, nonetheless). Indeed, the obtained *in vitro* dissolution rates vary widely with the choice of experimental parameters. We agree with the district court that Alza's evidence of *in vitro* dissolution rates is irrelevant absent evidence demonstrating that the *in vitro* system is a good model of actual *in vivo* behavior. On that point, Alza's evidence is severely lacking.

We therefore affirm the district court's finding of noninfringement. In so doing we explicitly reject Alza's suggestion that the district court erred in failing to specifically state that not only did it find Alza's plasma concentration data and its "*in vitro*" data to be inadequate in isolation, but that it had also found the data to be inadequate in combination. Even if we were to entertain the suggestion

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that the district court was in fact unfamiliar with the basic precept that it is the totality of the evidence that it must consider in making factual determinations, we would merely conclude that where as here, if each of two pieces of evidence, assessed separately, is severely inadequate to support a proposition, when their probative values are tallied, they still fall short. While it is possible to envision cases in which two pieces of evidence may create great probative value synergistically, this is not one of those cases.

* * *

In conclusion, we affirm the judgment of the district court that the asserted claims of the '355 patent were invalid, and that notwithstanding, the patent was not infringed.

AFFIRMED.

Costs to Mylan.

- End of Case -

EXHIBIT D

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > ATD Corp. v. Lydall Inc., 48 USPQ2d 1321 (Fed. Cir. 1998)

ATD Corp. v. Lydall Inc., 48 USPQ2d 1321 (Fed. Cir. 1998)

48 USPQ2d 1321

ATD Corp. v. Lydall Inc.

U.S. Court of Appeals Federal Circuit

Nos. 97-1308, -1356

Decided October 6, 1998

159 F3d 534

Headnotes

PATENTS

[1] Patent construction -- Claims -- Defining terms (► 125.1305)

Term "embossments," as used in claims of patents for thermal insulation pads, means depressions or bumps that separate and form gap between at least some of foil layers in pads by point contact of embossments with adjacent layers, since specifications show and claims require that insulating gap between at least some of metal foil layers in pad is formed by embossments that space apart foil layers, since presence of embossments making contact with adjacent layers of foil to separate layers is described in specifications as material aspect of invention, and since use of heat-resistant mesh or scrim between some layers, even without embossments, does not defeat requirement of even broadest claims that pad contain at least two layers of foil bearing embossments that separate those layers.

[2] Infringement -- Literal infringement (► 120.05)

Federal district court properly granted summary judgment that accused thermal insulation does not literally infringe asserted claims of patents in suit, since claims require that at least two foil layers in insulation pads have "embossments" that separate and form gap between layers by point contact, since this separation function is express limitation of claims, and since, in accused product and method, there is no contact between impressed relief pattern on foil layers, which are separated by metal mesh, and any adjacent layer.

[3] Infringement -- Doctrine of equivalents -- In general (► 120.0701)

Substantial evidence supports jury's verdict that accused thermal insulation does not infringe asserted claims of patents in suit under doctrine of equivalents, since defendant presented expert testimony that metal mesh in accused product, which performs same function of separating foil layers of insulation pad as "embossments" of claims, does so in substantially different way to produce substantially different result, and that use of mesh preserves sheet reflectivity and results in greater crush resistance, providing advantages as well as differences.

[4] Patentability/Validity -- Anticipation -- Identity of elements (► 115.0704)

None of cited prior art references anticipate asserted claims of patents for thermal insulation, since none of them show combination of embossed insulating layers and compressed heat sink layers required by claims.

[5] Patentability/Validity -- Obviousness -- Combining references (► 115.0905)

Patentability/Validity -- Obviousness -- Secondary considerations generally (► 115.0907)

Patents for thermal insulation are not obvious over combination of prior art references cited by infringement defendant, even though "embossments" similar in general shape to those of patents have been used to space insulating layers of various forms, since some references cautioned against compressing layers in multilayer insulator, and none showed compressing layers to form heat sink as in patented product and method, since there is no evidence of teaching or suggestion to select components inventors selected, from crowded field of insulation technology, to produce product and method of patents, and since patented product met unsolved need and was quickly adopted by automotive industry.

[6] Practice and procedure in Patent and Trademark Office -- Prosecution -- Duty of candor -- Citation of references (► 110.0903.08)

Applicant did not engage in inequitable conduct by failing to cite prior art U.S. patent, or Patent Cooperation Treaty search report and prosecution records applying that patent to corresponding PCT application, in divisional application for patent in suit, since prior patent was cited in prosecution of parent application, and it is not inequitable conduct to fail to resubmit, in divisional application, information cited or submitted in parent, and since applicant was not required to resubmit documents relating to prior patent in record of PCT application when that patent was already of record in U.S. application; details of foreign prosecution are not additional category of material information.

JUDICIAL PRACTICE AND PROCEDURE

[7] Procedure -- New trial; JMOL (► 410.30)

Standard to be applied in determining whether admission of evidence in patent infringement

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action constituted harmless error is not whether there was "substantial evidence" of non-infringement without tainted evidence, since Fed.R.Civ.P. 61 defines harmless error as any error or defect in proceeding "which does not affect the substantial rights of parties"; admission of evidence is therefore reviewed for whether, under circumstances presented, it reasonably affected outcome of case.

[8] Procedure -- New trial; JMOL (► 410.30)

Admission of infringement defendant's patent as evidence that its products were substantially different from and superior to that covered by plaintiff's patents, under circumstances in which plaintiff was unable to present defense on substance of defendant's patent, does not warrant new trial, since, in view of correctly construed claims, reasonable jury could not have found either literal infringement or infringement under doctrine of equivalents, and admission of defendant's patent as evidence therefore did not affect outcome of case.

[9] Procedure -- Discovery -- In general (► 410.4001)

35 USC 282, which provides that party asserting invalidity of patent in suit must give notice of prior art relied upon as evidence of anticipation to adverse party at least 30 days before trial, does not override discovery schedule set under Federal Rules of Civil Procedure, since procedure set by court and agreed to by parties necessarily governs particular trial, and although Section 282 sets minimum period for identification of prior art to be introduced as evidence of anticipation, specific judicial directive for timing of discovery establishes procedures to which parties are bound.

Particular Patents

Particular patents -- General and mechanical -- Thermal insulation

5,111,577, Sheridan and Ragland, pad including heat sink and thermal insulation areas, judgment of non-infringement *affirmed*; judgment of invalidity *reversed*.

Case History and Disposition

Page 1322

Appeal from the U.S. District court for the Eastern District of Michigan, Rosen, J.; 43 USPQ2d 1170 .

Action by ATD Corp. against Lydall Inc. for patent infringement. Plaintiff appeals from judgment holding certain claims of patents in suit invalid and not infringed, and defendant cross-appeals from holding that inequitable conduct was not established. Affirmed in part and *reversed* in part; Clevenger, J., concurring in part and dissenting in part in separate opinion.

Attorneys

Bruce T. Wieder, Frederick G. Michaud Jr., Eric H. Weisblatt, and Ronni Jillions, of Burns, Doane, Swecker & Mathis, Alexandria, Va., for plaintiff-appellant.

Barry L. Grossman, of Foley & Lardner, Washington, D.C.; William P. Atkins, of Pillsbury, Madison & Sutro, Washington, for defendant-cross appellant.

Judge

Before Rich, Newman, and Clevenger, circuit judges.

Opinion Text

Opinion By:

Newman, J.

ATD Corporation appeals the final judgment ¹ of the United States District Court for the Eastern District of Michigan, holding the claims in suit of United States Patents No. 5,011,743 (the '743 patent) and No. 5,111,577 (the '577 patent), both entitled "Pad Including Heat Sink and Thermal Insulation Areas," invalid and not infringed. We affirm the rulings of non-infringement and reverse the rulings of invalidity. On Lydall's cross-appeal we affirm that inequitable conduct was not established. The challenged evidentiary rulings are sustained.

¹ *ATD Corp. v. Lydall, Inc.*, 43 USPQ2d 1170 (E.D. Mich. 1997).

BACKGROUND

The '743 patent relates to a flexible insulating pad that includes heat sink and thermal insulation areas. It is described as particularly useful for providing "hot spot" insulation, and is used primarily in automotive underbodies. It achieved prompt commercial acceptance, as an economical and efficient structure for

dissipating heat. Two of the patent drawings are reproduced below. Fig. 1 a top view and Fig. 2 a cross section of the patented pad:

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The thermal insulation area 5 is made of layers of metal foil 2 separated by air gaps, and the heat sink area 4 is formed by compressing the edges of the foil layers. The depressions at 6 are called "embossments," and the dashed lines at 11 represent optional layers of heat-resistant scrim.

Claims 1 and 3 of the '743 patent are at issue, shown with emphases added to highlight the disputed subject matter with respect to infringement; all of the other claim elements and limitations are conceded to be present in the accused pads:

1. A pad including thermal insulation and heat sink areas comprising:

a plurality of layers of metal foil forming a stack wherein said layers are arranged one above another in a vertical direction,

said stack including at least one heat sink area and at least one thermal insulating area adjacent to said heat sink area,

said layers providing better heat condition in said vertical direction at said heat sink area than at said insulating area,

at least two of said layers including *a plurality of embossments therein separating said layers in said insulating area so as to provide gaps therebetween* ,

one of said layers in said insulating area being adjacent to and not metallurgically bonded to another one of said layers,

said heat sink area comprising a compressed portion of said stack.

3. The pad of claim 1, wherein said heat sink area at least partly surrounds said insulating area and said layers in said heat sink area are interengaged with each other by securing means.

The '577 patent is a division of the '743 patent, and relates to the manufacture of the pad. Claims 1, 11, and 19 of the '577 patent are as follows, with emphases added to show the usages of "embossments," the only point of dispute.

1. A method of making a heat insulating pad having insulating and heat sink areas, comprising:

a step of assembling a plurality of layers of metal foil in a stack wherein said layers are arranged one above another in a vertical direction, *at least two of said layers being separated from each other by a plurality of embossments* on at least one of said layers;

a step of compressing at least one portion of said stack such that heat sink and insulating areas are

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formed therein with said layers providing better heat conduction in said vertical direction at said heat sink area than at said insulating area, *said embossments in said insulating area separating said layers so as to provide a gap therebetween* ; and

a step of securing said layers together in said heat sink area, said securing step including interengaging said layers in said heat sink area with each other.

11. A method of making a heat insulating pad having insulating and heat sink areas, comprising:

a step of assembling a plurality of layers of metal foil in a stack wherein said layers are arranged one above another in a vertical direction, *at least two of said layers being separated from each other by a plurality of embossments* on at least one of said layers; and

a step of compressing at least one portion of said stack such that heat sink and insulating areas are formed therein with said layers providing better heat conduction in said vertical direction at said heat sink area than at said insulating area, *said embossments in said insulating area separating said layers so as to provide a gap therebetween* .

19. The method of claim 11, wherein said assembling step comprises assembling a plurality of layers of metal foil which make said pad flexible.

The accused Lydall pads contain heat sink and insulating areas, in accordance with the claims, and are the same as the ATD pads except that the Lydall foil layers are separated by knitted or woven mesh instead of by depressions in the foil. ATD argues that due to compression forces applied during manufacture, the Lydall foil layers are "embossed" with the impressions of the intervening mesh. ATD states that these "embossments," along with the mesh reach to the adjacent layers of foil, and thus that the product and process claims are infringed, literally or in accordance with the doctrine of equivalents.

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Upon ATD's suit for patent infringement, Lydall raised the defenses of non-infringement, invalidity, and unenforceability. On cross-motions for summary judgment, the district court granted Lydall's motion that there was not literal infringement and no willful infringement. The district court also granted ATD's motion that there was not inequitable conduct in the prosecution of the patents. The court ruled that there were genuine issues of material fact on the issue of infringement under the doctrine of equivalents and the issue of validity; these issues were tried to a jury. The jury found that Lydall did not infringe, under the doctrine of equivalents, claim 3 of the '743 patent, nor claims 1, 5-7, 11, or 19 of the '577 patent. The jury deadlocked on the issue of infringement by equivalents of claim 1 of the '743 patent. The jury also found that claims 1 and 3 of the '743 patent and claims 1, 11, and 19 of the '577 were invalid based on prior art. The district court entered judgment accordingly, and denied all post-trial motions. Each side appeals the rulings adverse to it.

I

LITERAL INFRINGEMENT

Determination of the issue of literal infringement involves the steps of first construing the claims, a matter of law assigned to the judge whether or not a jury trial has been demanded, and then applying the construed claims to the accused device, a factual determination performed by the jury. *See Markman v. Westview Instruments, Inc.* , 52 F.3d 967, 976, 34 USPQ2d 1321, 1326 (Fed.Cir. 1995) (in banc), *aff'd* , 517 U.S. 370, 38 USPQ2d 1461 (1996). In this case, as often occurs, the question of literal infringement was resolved upon the court's construction of the claims. *See id.* at 999, 34 USPQ2d at 1346 (Newman, J., dissenting) ("Deciding the meaning of the words used in the patent is often dispositive of the question of infringement.") Thus a court may grant summary judgment when, upon construction of the claims and

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with all reasonable factual inferences drawn in favor of the non-movant, it is apparent that only one conclusion as to infringement could be reached by a reasonable jury. See Fed.R.Civ.P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (purpose of summary judgment is to avoid an unnecessary trial); *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1476, 45 USPQ2d 1429, 1431 (Fed.Cir. 1998) (affirming ruling that given correct claim construction no reasonable jury could find literal infringement). Claim construction is determined *de novo* on appeal, *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1174 (Fed.Cir. 1998) (in banc); *Markman*, 52 F.3d at 979, 34 USPQ2d at 1329, as is the correctness of the grant of summary judgment, *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532, 41 USPQ2d 1001, 1007 (Fed.Cir. 1996).

A. Claim Construction

The claims of both the '577 and '543 patents recite layers of metal foil having "a plurality of embossments" that separate the layers and establish gaps of insulating air between the layers. Lydall's position is that its foil layers are not "embossed"; ATD argues that they are, and that the district court erred in its construction of this term, leading to error in the ensuing decisions of non-infringement.

The district court drew on the two patent specifications for the meaning of "embossments" as used in the claims. See *Slimfold Mfg. Co. v. Kinkead Industries, Inc.*, 810 F.2d 1113, 1116, 1 USPQ2d 1563, 1566 (Fed.Cir. 1987) (claims are understood in light of the specification of which they are a part). When "the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term." *Multiform*, 133 F.3d at 1478, 45 USPQ2d at 1433. However, when such definition is challenged it is often appropriate, despite facial clarity and sufficiency of the specification and the prosecution history, to receive evidence of the meaning and usage of terms of art from persons experienced in the field of the invention. See Fed.R. Evid. 702-706.

The specifications of both patents in suit define the embossments as "depressions" and "bumps or projections," the numbers referring to Fig. 2 *supra* :

The embossments 6 form depressions on one side of a respective one of the layers 2 and bumps or projections on an opposite side of the respective layer.

'743 patent, col. 7, lines 37-39; '577 patent, col. 7, lines 41-44. The district court observed that this definition is consistent with the dictionary definition of "emboss" as meaning to "raise in relief from a surface." ATD argues that this definition supports its position, since Lydall's foil layers have "bumps and indentations." ATD argues that there is no reason to believe that the inventor

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used the term differently from its dictionary meaning, leaving no ambiguity and thus no need for "claim construction." ATD states that the district court erred in law in construing "embossments" as also requiring that the bumps and indentations reach from layer to layer of the foil. Thus ATD argues that since the claims are not ambiguous, and since "embossments" has a clear meaning, it is incorrect to add to the definition of "embossments" the requirement that they also serve to separate the layers of metal foil by the depth of the embossments that contact the adjacent layer of foil.

The specifications teach that the embossments make point contact between the adjacent layers of foil:

The pad 1 can include two layers 2 only one of which includes the embossments 6. In a preferred embodiment, however, at least two of the layers adjacent to each other include a pattern of the embossments 6, the layers being offset with respect to each other such that at least some of the embossments are not aligned in the vertical direction. With this arrangement, the layers 2 can be provided in point contact to minimize heat transfer therebetween in the vertical direction A.

'743 patent, col. 7, lines 9-17; '577 patent, col. 7, lines 13-21. The district court also reviewed the patent drawings, and correctly described them as showing "the embossments as being raised reliefs on the

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various layers such that the embossments come in direct point contact with adjacent layers (Figures 2 and 5 of the '743 and '577 patents.)" The court concluded that "embossments" as used in the claims require raised reliefs that separate adjacent layers of foil by point contact.

ATD states that the district court erroneously incorporated into the definition of "embossments" in the claims in suit the structural feature of "point contact" from non-asserted claim 11 of the '743 patent, which reads:

11. The pad of claim 1, wherein said pad is flexible and at least some of said embossments form depressions on one side of a respective one of said layers and bumps on an opposite side of said respective layer, *said embossments providing point contact between the layers* .

(Emphasis added.) ATD argues that point contact is described in the specification as simply a preferred embodiment, and is not a limitation to the claims that do not include it. ATD states that a definition of embossments without point contact is also supported by the description in the '743 and '577 specifications of an embodiment wherein layers of a heat-resistant mesh or scrim are interposed between foil layers. ATD states that since claim 1 is generic to the various embodiments shown in the specification, it was an error of law to restrict the broadest claim to the embodiment illustrated in Fig. 2 wherein the embossments are in point contact with adjacent foil layers.

Lydall responds that the mere fact that non-asserted claim 11 specifically states that the embossments are in point contact does not preclude the construction of claim 1 as requiring that the embossments separate the layers. Lydall points out that for the embodiment in which ATD uses mesh between some foil layers, the specification shows that at least some of the layers are separated by point contact of the embossments. Non-asserted dependent claim 14 of the '743 patent, which specifies one or more layers of scrim, also incorporates the claim 1 limitation of at least two "layers including a plurality of embossments therein separating said layers in said insulating area so as to provide gaps therebetween."

The separation of layers and ensuing provision of insulating gaps arise from the point contact. Thus we agree that the correct interpretation of the claims in suit is that, whether or not mesh is used between some of the foil layers, the embossments serve to separate at least some of the layers. The doctrine of claim differentiation can not broaden claims beyond the scope that is supported by the specification. *Multiform Desiccants* , 133 F.3d at 1480, 45 USPQ2d at 1434 ("claim differentiation can not broaden claims beyond their correct scope"); *Tandon Corp. v. United States Int'l Trade Comm'n* , 831 F.2d 1017, 1023, 4 USPQ2d 1283, 1288 (Fed.Cir. 1987) ("Whether or not claims differ from each other, one can not interpret a claim to be broader than what is contained in the specification and claims as filed.") The presumption that separate claims have different scope "is a guide, not a rigid rule." *Autogiro Co. of America v. United States* , 384 F.2d 391, 404, 155 USPQ 697, 708 (Ct.Cl. 1967).

ATD also argues that the district court improperly added a method limitation to the product claims when it interpreted the method claims as requiring the embossments to be made on the metal sheets before the assembly process. The district court held that "[t]he specifications make clear that the 'embossments' as contemplated under the patents are made on the metal sheets *prior to any assembly process*" (district court's emphasis), and that "the '577 patent is very clear on pre-assembly embossment." The

court cited the specification of the '577 patent:

The method according to the invention can also include a step of embossing a plurality of the layers 2 such that a plurality of the embossments 6 are formed therein, the embossing step being performed by simultaneously embossing a plurality of overlapping sheets 2 of the metal foil, *each of the sheets after the embossing step comprising a respective one of the layers* . The embossments can be provided in a random or uniform repeated pattern. It is also within the scope of the invention to emboss each sheet separately. *The embossments can be provided by passing a single sheet or stack of sheets between a pair of rollers having the desired embossment pattern thereon* .

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'577 patent, col. 8, lines 32-44 (district court's emphasis).

This aspect is relevant to both the product and the method claims, for it was not disputed that in the Lydall pad a pattern of impressions is produced on the metal foil after the foil is assembled into layers, by compression of the foil against the intervening mesh. The specifications make clear that the "embossments" of the '743 and '577 patents are "something more than 'impressions' on the surface of the foil layers which are merely 'incidental,' " in the district court's words. The claims require that the "embossments" be deep enough to separate the adjacent layers of foil; the product claims are not dependent on how the embossments are made, and were not construed otherwise.

[1] Upon plenary review we confirm the district court's claim construction. The '743 and '577 specifications show and the claims require that the insulating gap between at least some of the metal foil layers is formed by the embossments that space apart the foil layers. In the patent specifications the presence of embossments making contact with adjacent layers of foil to separate the layers is described as a material aspect of the invention. The use of a mesh or scrim between some of the layers, even without "embossments" in those layers, does not defeat the requirement of even the broadest claims that the pad contain at least two layers of foil bearing embossments that separate the layers. Claim 1 of the '743 patent, correctly interpreted, embraces generically the use of mesh between some of the foil layers, but also requires that embossments on some of the foil layers make contact with and separate adjacent foil layers. All of the claims of both patents require embossments that serve this function, and the specifications make clear that this is essential to the patented invention. We conclude, as did the district court, that "embossments" as used in the '743 and '577 patents means depressions or bumps that separate and form a gap between at least some of the foil layers by point contact of the embossments with adjacent layers. This definition applies to all the claims in suit.

B. Application to Accused Devices

We give plenary review to the district court's grant of Lydall's motion for summary judgment of non-infringement, reapplying the standard for summary adjudication as applied by the district court.

Lydall's original product (discontinued after June 1, 1995) included an outer layer of metal foil with a "decorative pattern" in relief. The ensuing product did not include this outer pattern in relief. The court found that these indentations "projected outward, only -- i.e., they did not provide point contact with adjacent interior solid metal layers, nor did they provide gaps between the layers." The court held that although these outer layers were "embossed" in the ordinary usage of the word, they did not contain "embossments" within the meaning of that term in the patents. We agree that no reasonable jury could have found otherwise.

In the Lydall product the metal foil layers are each separated by an intervening layer of metal mesh. When the mesh is pressed between the foil layers during the assembly process, there is created a patterned impression of the mesh on the smooth metal foil sheets. Applying the claims as construed, the district court found that these impressions do not constitute "embossments" as that term is used in the ATD claims, and that the Lydall impressions are "merely incidental to the contact of the mesh with the surface of the metal layers." The district court found that in the Lydall product it is the mesh that separates the layers and creates the insulating gap, and not the embossed depressions that are formed in the metal foil where it is pressed against the mesh. The court found that there was no point contact between the Lydall layers, as required by the court's claim construction, for "[t]he metal mesh in fact prevents all contact between the adjacent metal sheet layers." The court concluded that because there were no embossments providing point contact, summary judgment of no literal infringement was appropriate because an essential limitation of the claims was absent from the accused structure and method.

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ATD argues that the Lydall embossments literally meet the claims' requirement of embossments, not only in the plain meaning of "emboss," but also because the Lydall embossments contribute along with the mesh to the gaps between the foil layers. ATD stresses that point contact is not a limitation to the claims in suit, and that the presence of the wire mesh between the foil layers of the Lydall product does not avoid literal infringement because there are embossments on the Lydall foil layers. ATD also argues that the issue of whether the Lydall embossments contribute to the gap between the layers of foil presents a question of material fact that could not be summarily resolved against ATD, and requests trial of this question.

[2] It is not disputed that in the Lydall product and method there is no contact between the impressed relief pattern on the foil layers, and any adjacent layer. There are no "embossments," as we and the district court construe the term as used in the patents, to separate the foil layers. This separation function is an express limitation of the asserted claims. In view of its absence from the accused product and method, no reasonable jury could have found that the asserted claims are literally infringed by the Lydall product or method. See *Cole*, 102 F.3d at 532, 41 USPQ2d at 1007 (affirming summary ruling of non-infringement when "accused products do not literally meet all of the claim limitations"). Therefore, summary judgment of no literal infringement was properly granted.

II

INFRINGEMENT BY EQUIVALENTS

The question of infringement in terms of the doctrine of equivalents was given to the jury. The district court construed the term "embossments," in Jury Instruction No. 25, as follows:

25. . . . You are instructed that embossments are purposefully created patterns directly formed on individual foil layers that produced depressions on one side of a respective layer and bumps or projections on the opposite side of the respective layer. The embossments create projections providing direct point contact with adjacent layers. The embossments must be large enough to separate the layers and provide gaps between the layers.

ATD argues that the district court incorrectly construed the claims, thereby distorting the jury's finding of non-infringement and providing an incorrect basis for the jury verdict. See *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568, 41 USPQ2d 1225, 1236 (Fed.Cir. 1997) (reviewing whether jury verdict was in accordance with correct claim construction). As we have discussed, the district court's construction of the term "embossments" correctly included the requirement of point contact.

[3] On the issue of equivalency the jury was instructed as follows:

27. . . . Under the doctrine of equivalents, you must find that there are insubstantial differences between the patent claims and the alleged infringing product or method of making the product. In this regard, you may consider whether the defendant's product or method performs (1) substantially the same function (2) in substantially the same way (3) to produce substantially the same result when compared to the plaintiff's patented product or method, even though they may differ in name, shape or form.

An accused product or method does not infringe under the doctrine of equivalents if it performs the function and achieves the result in a substantially different way than the claimed invention.

The doctrine of equivalents does not involve the application of a formula and is not an absolute to be considered in a vacuum. Rather, the question of whether one component of the allegedly infringing product or method is equivalent to an element in the patented claim is a factual matter. It requires you to consider the context of the entire claim. Your answer will depend upon the drawings and written description, the patent application history, the prior art and all the circumstances of this case.

* * * *

Other factors to be considered in determining infringement is the known interchangeability of the accused and claimed elements or other objective technological evidence demonstrating that the substitute nevertheless represents a change that one of ordinary skill in the art would have considered "insubstantial" at the time of infringement. Evidence of copying and evidence of "designing around" are also relevant to the question of infringement under the doctrine of equivalents.

The issue of infringement under the doctrine of equivalents was fully litigated. One of Lydall's expert witnesses testified that the Lydall mesh is substantially different from the ATD embossments. He testified that

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although the Lydall mesh and the ATD embossments perform the function of separating the foil layers, they do so in substantially different ways, leading to substantially different results. According to Lydall's expert, the use of the Lydall mesh preserves sheet reflectivity and results in greater crush resistance, providing advantages as well as differences. ATD disputed this evidence and its significance, and stressed that Lydall used the combination of a heat sink and insulator, the most important part of the ATD invention. Reviewing the record, we conclude that there is substantial evidence to support the jury verdict that there is not infringement under the doctrine of equivalents.² That judgment is *affirmed*.

² The concurring/dissenting opinion draws analogy to a case styled *Vehicular Technologies*. However, the cases are not the same. In the case at bar the function of the embossments separating the layers is stated in the claims, whereas in *Vehicular* the function of back-up is stated only in the descriptive text of the specification.

III

PATENT VALIDITY

The jury verdict was that claims 1 and 3 of the '743 patent and claims 1, 11, and 19 of the '577 patent were invalid based on prior art. The district court entered judgment accordingly.³ The evidence is reviewed to ascertain whether the jury's express or implicit factual findings were supported by substantial evidence, and whether the legal conclusion represented by the verdict was adequately based on supported findings, accompanied by correct application of the law to the facts. *See Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 619, 225 USPQ 634, 636 (Fed.Cir. 1985) ("In reviewing a decision denying a motion for judgment notwithstanding the verdict, we do not approach the issues as if there had been no trial. We review the evidence as a whole, and ascertain whether the verdict is in accordance with law, and whether there was substantial evidence in support of the jury's verdict.") In so doing, we resolve any disputed facts and draw all reasonable factual inferences in favor of the jury verdict. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1235, 9 USPQ2d 1913, 1919 (Fed.Cir. 1989); *DMI, Inc. v. Deere & Co.*, 802 F.2d 421, 425, 231 USPQ 276, 278-79 (Fed.Cir. 1986).

³ Although we have *affirmed* the judgment of non-infringement we review the merits of the judgment of invalidity, in accordance with *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 98, 26 USPQ2d 1721, 1728 (1993).

Although the verdict form did not state the ground on which the jury relied, Lydall had raised grounds of both anticipation and obviousness, and the parties have *argued* both of these grounds on appeal.

Anticipation

A patent is invalid for anticipation when the same device or method, having all of the elements and limitations contained in the claims, is described in a single prior art reference. *Richardson*, 868 F.2d at 1236, 9 USPQ2d at 1920; *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed.Cir. 1984). An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. See *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed.Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 1566, 1567, 7 USPQ2d 1315, 1317 (Fed.Cir. 1988). Lydall relied on seven references, as follows:

The Collier U.K. Patent No. 126,780, entitled *Improvements in or connected with the Construction of Boxes or Cases or like objects and of the Floors, Roofs, Walls, Partitions or other Parts of Railway or other Vehicles or like objects*, was cited in the prosecution of the '743 patent. Collier, discussing insulation of railway cars, shows the use of embossed projections to separate metal layers for insulation, but does not describe foil layers and heat sink areas, as required by each of the claims.

The Meckenstock German utility model shows a heat shield for gas-exhausting parts of motor vehicles. Meckenstock describes the use of two sheet metal plates, at least one of them including projections to separate the plates, but shows no foil layers as required by each of the claims.

The ASTM (American Society for Testing Materials) Pub. C 667-80, entitled *Standard Recommended Practice for Prefabricated Reflective Insulation Systems for Equipment and Pipe Operating at Temperatures Above Ambient Air*, describes a rigid inner and outer case protecting embossed liners, which may be foil. The reference does not show compressed foil to form heat sink areas, as required by each of the claims, and cautions against such deformation of the liners.

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The ASTM Pub. C 740-82 entitled *Standard Practice for Evacuated Reflective Insulation in Cryogenic Service*, describes an insulator made from multiple layers of metal foil, the foil layers having embossments that separate the layers and form air gaps between the layers. This reference does not show compressing the layers to form heat sinks, and cautions against compression of the layers. Neither of the two ASTM references shows compressed layers of foil creating heat sink areas accompanying the insulating areas.

The article by F.E. Swalley et al., entitled *Practical Problems in Design of High-Performance Multilayer Insulation System for Cryogenic Stages*, *Advances in Cryogenic Engineering*, Vol. 10 at 208 (1965), describes a multilayer insulation system for cryogenic stages, again showing projections to space the layers apart, but does not show compressed layers of foil creating heat sink areas.

The article by L.D. Stimpson et al., entitled *Predicting Spacecraft Multilayer Insulation Performance from Heat Transfer Measurements*, *Heat Transmission Measurements in Thermal Insulations*, ASTM STP 544 (1974), is directed to multilayer insulation blankets in spacecraft. It describes multilayered insulation as "a series of radiation shields with low-conductivity spacers." Lydall does not discuss the substance of the Stimpson article in its brief, and we agree with ATD that Stimpson does not disclose an insulating area together with a heat sink area.

Logan et al. U.S. Patent No. 4,489,852 describes a cooking utensil, such as a cookie sheet, "of a double walled construction providing an insulating layer or volume of air therebetween," but does not show a stack of foil layers as called for by the claims. The parties stipulated that Logan et al. "do not disclose

every element of the claims of the ATD patents arranged as in the claims.”

[4] None of these references meets the criteria of anticipation, for none show the combination of embossed insulating layers and compressed heat sink areas. There was not substantial evidence to support a verdict of invalidity based on anticipation.

Obviousness

Obviousness is a legal conclusion based on underlying facts of four general types, all of which must be considered by the trier of fact: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of nonobviousness. See *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966); *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1270, 20 USPQ2d 1746, 1750 (Fed.Cir. 1991); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1566-68, 1 USPQ2d 1593, 1595-97 (Fed.Cir. 1987).

Determination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. There must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor. See *Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc.*, 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed.Cir. 1994) (“When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination.”); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 935, 15 USPQ2d 1321, 1324 (Fed.Cir. 1990) (the prior art must suggest to one of ordinary skill in the art the desirability of the claimed composition); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed.Cir. 1985).

ATD argues that there was not substantial evidence to support a finding that the prior art contained a teaching or suggestion to combine selected portions of the prior art in order to create the patented structure or method. ATD argues that the jury must have improperly reasoned with the hindsight of ATD’s successful accomplishment. Lydall relied on the same group of references as for anticipation. However, Lydall points to no evidence supporting the obviousness determination, other than the conclusory opinion of its expert witness.

[5] We observe that embossments, similar in general shape to those of the ATD patents, have been used to space insulating layers of various forms. However, some of the cited references cautioned against compressing the layers in a multilayer insulator, and none showed compressing the insulating layers to form a heat sink as in the patented device and method. Lydall does not direct us to any evidence of a teaching or suggestion to select the components that ATD’s inventors selected, from the crowded field of insulation technology, to produce the product and method of the ‘743 and ‘577 patents. Lydall’s witnesses

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themselves expressed the view that such compression would be undesirable, providing cogent evidence that one of ordinary skill would not have deemed it obvious to compress the layers of an insulating device for heat sink purposes. Absent substantial evidence of such teaching or suggestion in the prior art or in the general knowledge of persons of ordinary skill in the field, there was not substantial evidence to support the jury’s verdict of obviousness. It was undisputed that the product met an unsolved need and was quickly adopted by the automotive industry, this commercial success also weighing against obviousness.

Because there was not substantial evidence supporting the verdict on the ground of either anticipation or obviousness, the judgment of invalidity is *reversed*.

IV

INEQUITABLE CONDUCT

Determination that a patent applicant engaged in inequitable conduct before the Patent and Trademark Office requires, as threshold findings of fact, both that the applicant failed to disclose material information to the PTO, and that he intended thereby to mislead or deceive the patent examiner into granting the patent. Materiality of the non-disclosed information, and culpable intent, must be established by clear and convincing evidence. When these facts are established, the court will weigh the findings and their premises and decide, in the court's exercise of discretion, whether to hold the patent unenforceable. *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872, 9 USPQ2d 1384, 1389 (Fed.Cir. 1988) (in banc). We review the district court's ruling on the ultimate issue of inequitable conduct on the standard of abuse of discretion, *Kingsdown*, 863 F.2d at 876, 9 USPQ2d at 1392, while review of the underlying facts is on the clearly erroneous standard, with due consideration of the burden to establish both materiality and intent to deceive by clear and convincing evidence.

The district court ruled on summary judgment that the '743 and '577 patents were not unenforceable for inequitable conduct. Lydall appeals this ruling, stating that there were disputed facts as to whether certain information was material to patentability, and therefore that the issue was not amenable to summary disposition. Although the premises of inequitable conduct require findings based on all the evidence, a procedure that may preclude summary determination, see *Kangaroo U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1577, 228 USPQ 32, 35 (Fed.Cir. 1985), a motion for summary judgment may be granted when, drawing all reasonable factual inferences in favor of the non-movant, the evidence is such that the non-movant can not prevail.

Lydall argued that during prosecution of the '577 divisional application ATD withheld U.S. Patent No. 2,212,481 to Sendzimir, as well as a PCT search report and prosecution records applying Sendzimir to the corresponding PCT application. Lydall argues that this inequitable conduct in prosecuting the '577 patent "infects" the '743 parent patent, and that both patents should be held unenforceable.

[6] The Sendzimir patent was cited in the prosecution of the '743 patent. Thus the district court found that ATD's failure to provide the Sendzimir information during the prosecution of the '577 divisional patent was not clear and convincing evidence of intent to deceive, observing that in accordance with M.P.E.P. Section 609 (Rev. 14, Nov. 1992) ⁴ a reference is not required to be resubmitted in prosecuting a divisional application:

⁴ Further elaboration of the rule was subsequently made. See M.P.E.P. Section 609 (Rev. 3, July 1997).

Section 609. . . . the patent examiner will consider information cited or submitted to the Office in a parent application when examining a continuing application, and a list of the information need not be submitted in the continuing application unless applicant desires the information to be printed on the patent.

In view of Section 609 it can not be inequitable conduct for an applicant not to resubmit, in the divisional application, the information that was cited or submitted in the parent application. See *Transmatic, Inc. v. Gulton Industries, Inc.*, 849 F.Supp. 526, 31 USPQ2d 1225 (E.D. Mich. 1994), *aff'd in pertinent part*, *rev'd in part*, 53 F.3d 1270, 35 USPQ2d 1035 (Fed.Cir. 1995) (a material reference that is already of record in parent application need not be resubmitted by the applicant in a continuing application). Nor was ATD required to submit the documents relating to Sendzimir in the record of the PCT application, when Sendzimir was already of record in the United States parent application. Although international search reports may contain information material to patentability if they contain closer prior art than that which was before the United States

examiner, it is the reference itself, not the information generated in prosecuting foreign counterparts, that is material to prosecution in the United States. The details of foreign prosecution are not an additional category of material information. See *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180, 33 USPQ2d 1823, 1828 (Fed.Cir. 1995) (duty to cite material references arising in related foreign applications).

We discern no clear error in the district court's ruling that because the Sendzimir reference was of record in the parent '743 application, and because M.P.E.P. Section 609 states that the information need not be resubmitted, there was not clear and convincing evidence of material withholding with intent to deceive. The summary judgment of no inequitable conduct is *affirmed*.

V

EVIDENTIARY RULINGS

Evidentiary rulings, when appealable, are reviewed under the criteria of the regional circuit, unless the evidentiary issue is unique to patent law or litigation and thus would benefit from national uniformity. See *National Presto v. West Bend Co.*, 76 F.3d 1185, 1188 n.2, 37 USPQ2d 1685, 1686 n.2 (Fed.Cir. 1996) ("On procedural matters not unique to the areas that are exclusively assigned to the Federal Circuit, the law of the regional circuit shall be applied.")

The abuse of discretion standard is applied to review of evidentiary rulings in the Sixth Circuit, as it is generally in the federal system. E.g., *Schrand v. Federal Pacific Elec. Co.*, 851 F.2d 152, 156-57 (6th Cir. 1988) ("This court applies an abuse of discretion standard in reviewing decisions of a trial court on the admission of evidence.") In addition, Fed.R.Civ.P. 61 provides, "No error in either the admission or the exclusion of evidence . . . is ground for granting a new trial or for setting aside a verdict . . . unless refusal to take such action appears to the court inconsistent with substantial justice." See *Schrand*, 851 F.2d at 156-57. Thus evidentiary decisions are reviewed for abuse of discretion, and may be reversed only when that abuse has led to harmful error or the denial of substantial justice. *Cooley v. Carmike Cinemas, Inc.*, 25 F.3d 1325 (6th Cir. 1994).

A

ATD asserts that the district court abused its discretion in allowing Lydall to present Lydall's U.S. Patent No. 5,424,139 ("the Lydall patent") as evidence that its products were substantially different from and superior to that covered by ATD's patents, and that substantial justice requires a new trial. ATD states that Lydall, by its tactics, denied ATD adequate time to respond to this evidence.

During discovery, for each of the 19 claims of the Lydall patent ATD submitted a request for admission, asking Lydall to admit that "each accused Lydall shield is made in accordance with" that claim of the Lydall patent. Lydall's response, for each claim, was "Denied." Lydall retained that position for five months after the close of discovery. Twenty-nine days before the start of trial, Lydall changed its responses to "Denied, except as to shields made with twisted expanded metal mesh." Based on this tardy change in position ATD moved in limine to exclude evidence of the Lydall patent. The motion was denied on the first day of trial, the district court stating that Fed.R.Civ.P. 36 binds a party to an admission, but not to a denial.

Lydall presented its patent as showing that its products were deemed patentable by the Patent Office, despite citation of the ATD patents, and for the comparative data in the Lydall patent which showed superiority of the accused products over the ATD product. Lydall presented five witnesses on these issues, giving substance to ATD's complaint about the tactics of the deliberately tardy identification of this issue. ATD states that by this tactic it was denied reasonable time to investigate the patent and its data, depose Lydall's witnesses, and present contrary evidence. ATD states that it was surprised, ambushed, and severely prejudiced. See *Erskine v. Consolidated Rail Corp.*, 814 F.2d 266, 272 (6th Cir. 1987)

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("One of the primary objectives of the discovery provisions embodied in the Federal Rules of Civil Procedure is elimination of surprise in civil trials.")

Lydall responds that the fact of separate patentability is admissible evidence, and thus that the district court acted within its discretion in admitting it. As for the tardiness of the discovery response, Lydall states that it properly denied ATD's requests for admission five months earlier because "each" accused product was not so made." Lydall states that it amended its answers consistent with Fed.R.Civ.P. 26(e).

ATD states that all of the accused Lydall products are within the Lydall patent claims, but for a few prototypes. Lydall does not dispute this point. Nor does Lydall cite a change in circumstance justifying the

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change in its interrogatory responses. Fed.R.Civ.P. 36 requires that "[a] denial shall fairly meet the substance of the requested admission, and when good faith requires that a party qualify an answer or deny only part of the matter . . . , the party shall specify so much of it as is true and qualify or deny the remainder." At the trial Lydall presented five witnesses on various aspects of its patent, its prosecution, and its comparisons with the ATD product. It is not reasonable to assume that Lydall planned this trial presentation within the twenty-nine days after it gave notice to ATD that it would rely on the patent. By no stretch of the Rules can Lydall or its counsel be deemed to have met reasonable standards of fairness, good faith, or professionalism.

[7] The district court, in its opinion denying ATD's request for a new trial, stated that even if there were error in admitting the evidence, it was harmless because there was substantial evidence supporting a verdict of non-infringement even without the evidence of the Lydall patent:

Even if Lydall's patent were erroneously admitted, such an error was harmless. An error in the admission of evidence is not a ground for granting a new trial where the admission of the evidence was harmless error. Fed.R.Civ.P. 61. In this case, Lydall presented substantial evidence at trial of its effort to design around ATD's patents and also presented substantial evidence which showed that Lydall's metal mesh separated layers in a different manner than ATD's embossments. This evidence would support a non-infringement verdict even without evidence of Lydall's '139 patent.

That is not the correct standard. The question is not whether there was "substantial evidence" of non-infringement without the tainted evidence. See 11 Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* Section 2806 at 65 (1984 & Supp. 1998) ("[O]n a motion for a new trial . . . the judge may set aside the verdict even though there is substantial evidence to support it.") The question is whether the admission of the Lydall patent affected the substantial rights of ATD, see Fed.R.Civ.P. 61; Fed.R. Evid. 103, or was indeed harmless error. See *Schrand*, 851 F.2d at 157. Rule 61 provides:

Harmless Error. No error in either the admission or the exclusion of evidence . . . is ground for granting a new trial or for setting aside a verdict . . . unless refusal to take such action appears to the court inconsistent with substantial justice. The court . . . must disregard any error or defect in the proceeding which does not affect the substantial rights of parties.

See also Fed.R.Civ.P. 59; 11 Wright & Miller, *supra* Section 2805 at 60 ("The importance of Rule 61 in its application to motions for a new trial cannot be overlooked. . . . [I]t is only those errors that have caused substantial harm to the losing party that justify a new trial. Those errors that are not prejudicial do not call for relief under Rule 59.") Therefore, we review whether the admission of this evidence, under the circumstances of the tardy discovery response, reasonably affected the outcome of the case. See *Schrand*, 851 F.2d at 157 (citing Fed.R.Civ.P. 61 and quoting *Jordan v. Medley*, 711 F.2d 211 (D.C. Cir. 1983) (Scalia, J.) ("assessment of the likelihood that the error affected the outcome of the case")); 1 Jack B. Weinstein & Margaret A. Berger, *Federal Evidence* Section 103.41 [2] (1998) ("In general terms, the test of whether a substantial right of a party has been affected is whether the error in question affected the outcome of the case.")

Circuit Courts in civil cases not involving constitutional error have articulated the standard in different ways, *e.g.*, whether it is "highly probable" that the erroneous admission did not affect the jury verdict, 1 Weinstein & Berger, *supra* Section 103.41 [2] at 103-53 n.32 (citing First, Third, and Eleventh Circuit cases); and whether it is "more probable than not" that the erroneous admission did not affect the jury verdict, 1 Weinstein & Berger, *supra* Section 103.41 [2] at 103-53 n.33 (citing Seventh, Eighth, Ninth, and Tenth Circuit cases). See also 3 James Wm. Moore, Federal Practice Section 61.02 [3] (1998) (standard of Rule 61 articulated in different ways). A number of factors have guided the courts in their determinations of whether error is harmless, including (1) whether erroneously admitted evidence was the primary evidence relied upon, (2) whether the aggrieved party was nonetheless able to present the substance of its claim, (3) the existence and usefulness of curative jury instructions, (4) the extent of jury argument based on tainted evidence, (5) whether erroneously admitted evidence was merely cumulative, and (6) whether other evidence was overwhelming. See 1 Weinstein & Berger, *supra* Section 103.41[5][a]-[h]; see also 11 Wright & Miller, *supra* Section 2885 [Rule 61] at 464 ("erroneous admission of evidence may be found not to have been prejudicial if the fact already had been shown by admissible evidence, or prejudice may be avoided by a curative instruction").

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The district court noted that it gave a limiting instruction to the jury concerning the Lydall patent:

23. Where there is an issued patent, the later issuance of a patent for a device or method raises no presumption of noninfringement of the previously issued patent. You may consider the later issued Lydall patent in your decision and give it the appropriate weight, but you must keep in mind that even where improvements and modifications are separately patentable, the improved device or method may still infringe the previously issued ATD patents.

A later patented device or method may include additional elements or steps beyond those claimed in the earlier issued patent. But if the later patented device or method contains each and every element of a claim of the earlier issued patent, or an equivalent of any element not literally included, then that claim of the earlier issued patent is infringed.

This instruction, however, did not relate to ATD's asserted inability to present a defense on the substance of the Lydall patent.

[8] Following a careful review of the trial record, we do not grant ATD's request for a new trial. Considering ATD's emphasis on the use of embossed foil layers to separate the layers, and the use of metal scrim in both the prior art and between one or two of the ATD outer layers in addition to the embossments, we are convinced that in view of the correctly construed claims, a reasonable jury could not have found either literal infringement or infringement under the doctrine of equivalents. On this basis the admission of the Lydall patent did not affect the outcome of this case.

B

Lydall cross-appeals the district court's refusal to allow Lydall to present U.S. Patent No. 2,037,813 (the Munters patent) as evidence of invalidity of ATD's patents. The court excluded the Munters patent because Lydall did not produce the reference during the designated discovery period.

According to the record, on December 20, 1994 ATD asked Lydall to identify each document Lydall considered to relate to validity and invalidity of the ATD patents. Lydall did not list the Munters patent in its reply of January 20, 1995. Subsequently, ATD served additional interrogatories and document requests, asking Lydall to identify prior art of which it was aware. Lydall did not list the Munters patent in any response. Following an extension, discovery closed on August 31, 1995. On December 1, 1995, Lydall served ATD with a "Notice of Prior Art Pursuant to 35 U.S.C. Section 282" listing the Munters patent. This was one month before a first rescheduled pretrial conference. Rejecting the submission, the

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court explained:

I want the record to be clear as to the basis that I am denying Lydall the opportunity to use that prior art at trial. The basis is not relevance. The basis is not any evidentiary ruling as to the value of this prior art. The basis is simply I'm exercising my discretion under the rule of the Federal Rules of Civil Procedure to preclude a party from relying on theories not made available or not disclosed to the opposing side.

Lydall states that although the Munters patent was not disclosed in response to any of the discovery requests or during the discovery period, it should not have been excluded because it was disclosed in accordance with 35 U.S.C. Section 282:

Section 282. . . . In actions involving the validity or infringement of a patent, the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit In the absence of such notice proof of said matters may not be made at the trial except on such terms as the court requires. . . .

Lydall argues that Section 282 overrides any discovery schedule set under the Federal Rules of Civil Procedure, because these Rules were instituted in 1938 whereas Section 282 was reenacted as part of the 1952 Patent Act. P.J. Federico, commenting on the 1952 Patent Act, reported the relationship in broad, and ambiguous terms:

The last paragraph of section 282 relating to the giving of notice of various details relating to certain defenses is based on part of the last paragraph of old R.S. 4920, with modifications. The old provision was in fact *superseded* by the Federal Rules of Civil Procedure [28 U.S.C.A.] but, as *modified*, has been reinstated.

[9] P.J. Federico, *Commentary on the New Patent Act* (1954), reprinted in 75 J. Pat. Trademark Off. Soc'y 161, 216 (1993). Since 1952, the matter has not been squarely resolved. In *Thermo King Corp. v. White's Trucking Serv., Inc.*, 292 F.2d 668, 674, 130 USPQ 90, 94 (5th Cir. 1961), that court

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referred to Section 282 as "coexisting" with the Federal Rules. We agree that they coexist. However, when the court has set and the parties have agreed to a discovery period, that procedure necessarily governs that trial. Thus although Section 282 sets a minimum period for the identification of prior art to be introduced as evidence of anticipation, a specific judicial directive for the timing of discovery establishes the procedures to which the parties are bound.

In *Eaton Corp. v. Appliance Valves Corp.*, 790 F.2d 874, 229 USPQ 668 (Fed.Cir. 1986) this court held that the trial court could, in its discretion, allow into evidence a reference that was not disclosed at least thirty days in advance despite Section 282, for in that case it was clear that the patentee was not surprised and was not prejudiced:

The objective of section 282's provision for advance notice is to prevent unfair and prejudicial surprise by the production of unexpected and unprepared-for prior art references at trial. To this end, section 282 is to be read with the Federal Rules of Civil Procedure.

790 F.2d at 879, 229 USPQ at 672 (citations omitted). The purpose of Section 282, like that of the Federal Rules, is to prevent unfair and prejudicial surprise, not to facilitate last-minute production of evidence. The district court in the instant case was well within its discretion in excluding the Munters patent, for the record shows that Lydall offered no reason to justify its submission long after the close of discovery. The solid entrenchment of the Federal Rules and the principles of orderly discovery weigh heavily against Lydall's argument that Section 282 governs the requirement of notice of prior art despite

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the elaborate discovery procedures, interrogatories, and explicit directives by which the trial was managed.

Costs

Costs are taxed against Lydall. See Fed.R.App.P. 39; Fed.Cir.R. 39.

AFFIRMED-IN-PART and REVERSED-IN-PART .

Clevenger, J., concurring in part and dissenting in part.

I agree with the conclusions that the claims in suit are not infringed, either literally or by equivalents, and are not invalid for anticipation or obviousness. I also agree that the claims in suit are not unenforceable for inequitable conduct, and that no error infects the challenged evidentiary rulings. I write separately to indicate a few points of disagreement as to the path followed by the court to the conclusions, and to highlight the point that the claim interpretation, with which I agree, drives both of the infringement conclusions.

There is no infringement in this case because the accused devices lack embossments that make contact with and separate adjacent foil layers. The claims recite "embossments therein separating said layers" The claim language itself does not speak of point contact. Separation by point contact, as the court's opinion amply demonstrates, is emphasized in the written description. The claim term "embossments" is thus properly understood to require the function of separation by point contact.

The claim interpretation analysis in this case follows from our recent decision in *Vehicular Technologies Corp. v. Titan Wheel Int'l, Inc.*, 141 F.3d 1084, 46 USPQ2d 1237 (Fed.Cir. 1998). In that case, the key claim language called for two concentric springs in a spring assembly, and the written description clearly required that the second spring have a back-up spring function. We held in *Vehicular Technologies* that the back-up function of the second spring affects the range of equivalents available to the patentee. *Id.* at 1091. So it is in this case, as well. Here, the same claim interpretation analysis requires the embossments to function by point contact, a claim requirement that likewise affects the range of equivalents. Because of this analysis, no reasonable juror could find infringement of claim 1 of the '743 patent under the doctrine of equivalents. As the court notes, the jury deadlocked on that infringement question. The issue was preserved below by post-verdict motions for judgment as a matter of law, and ATD preserves the issue on appeal by challenging the denial of its motion for a new trial on the question of infringement by equivalents.

We need not remand the deadlocked equivalents issue, however, because the claim as interpreted requires point contact to achieve separation of the layers. A claim of infringement by equivalents cannot succeed unless each limitation of a claim is met by an equivalent. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 41 USPQ2d 1865 (1997) (adopting sub silentio the "all elements" rule of *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 225 USPQ2d 552 (Fed.Cir. 1987) (*in banc*)). Because the accused devices lack any equivalent to the function of point contact, they cannot infringe

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claim 1 as a matter of law. See *Vehicular Technologies* 141 F.3d at 1090.

With regard to the issue of inequitable conduct, the district court made no explicit ruling on the materiality of the allegedly nondisclosed matter. *ATD Corp. v. Lydall, Inc.*, No. 94-CV-74320, slip op. at 43-46 (E.D. Mich. Jan. 9, 1995) (Opinion and Order Regarding Motions for Summary Judgment). Instead, the district court hinged its decision on the absence of proof of the requisite intent to deceive. *Id.* I thus would not dwell on the issue of materiality, as does the court, but instead would simply affirm the district court decision on its stated ground.

I disagree with the court's view that the district court applied an incorrect standard to test the new trial

motion. In the opinion and order denying the Rule 59 motion, the trial court set out the same law that this court states is governing. *Compare ATD Corp. v Lydall, Inc.*, 43 USPQ2d 1170, 1173, 1997 WL 111783, *3 (E.D. Mich. 1997) with the Maj. Op. at 29-30. The trial court then applied that "correct" law and determined that the alleged improper admission of Lydall's patent did not affect the substantial rights of ATD, because sufficient other evidence was before the jury to sustain its verdict of noninfringement by equivalents. *ATD Corp.*, 43 USPQ2d at 1173-79. In a footnote at the end of the discussion of the issue, the district court's opinion merely comments that even if there had been error in admitting Lydall's patent, the error would have been harmless. *Id.* at 1175 n.6. That comment is unrelated to the correct legal standard that the district court used to decide the Rule 59 motion, and cannot form a predicate for criticism of the district court.

Finally, I do not join the decision to tax costs to Lydall. Although the court speaks harshly of Lydall's conduct at trial, redress for trial court conduct properly lies in the trial court, not here. I am unaware of any reason to impose costs on Lydall.

- End of Case -

RELATED PROCEEDINGS APPENDIX

NONE